

10/11/2002 Simon, Paul O.

10/11/2002 Simon, Paul O.

1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE SOUTHERN DISTRICT OF OHIO  
3 WESTERN DIVISION AT CINCINNATI  
4 - - - - - x  
5 DURAMED PHARMACEUTICALS, INC., :  
6 Plaintiff, :  
7 vs. :  
8 WYETH-AYERST LABORATORIES, INC., :  
9 Defendant. : PAGES 1 - 275  
10 - - - - - x  
11  
12 HIGHLY CONFIDENTIAL  
13  
14 Videotape Deposition of PAUL SIMON  
15 Washington, D.C.  
16 Friday, October 11, 2002  
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22 Reported by: Susan D. Ashe, RMR Job No. 148412

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14 BY: GORDON DOBIE, ESQ.  
15  
16 ALSO PRESENT: William Lobb  
17 Robert Cherouny, Videographer  
18  
19  
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7 Friday, October 11, 2002  
8 9:13 a.m.  
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10  
11 Videotape Deposition of PAUL SIMON, held at the law  
12 offices of:  
13  
14  
15 Arnold & Porter  
16 555 Twelfth Street, N.W.  
17 Washington, D.C.  
18  
19  
20 Pursuant to notice, before Susan D. Ashe, Registered  
21 Merit Reporter, a Notary Public of the District of  
22 Columbia.

1 C O N T E N T S  
2  
3 EXAMINATION OF PAUL SIMON BY: PAGE:  
4 MR. DOBIE: 6  
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6  
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PROCEEDINGS

(Defendant's Exhibit Number 1075 was marked for identification.)

VIDEOGRAPHER: This is Tape No. 1 of the videotape deposition of Paul Simon, taken by the defendants, in the matter of Duramed Pharmaceuticals, Inc., versus Wyeth-Ayerst Laboratories, in the United States District Court for the Southern District of Ohio, Western Division at Cincinnati. Case number is C-1-00-735.

This deposition is being held at the offices of Arnold & Porter, 555 Twelfth Street, Northwest, Washington, D.C., on today's date -- which is October 11, 2002; and the time is approximately 9:13 a.m.

And my name is Robert Cherouny, from the firm of Esquire Deposition Services. And I'm the certified legal video specialist.

And the court reporter is Susan Ashe, also in association with Esquire.

And will the counsel please introduce

Have you ever had your deposition taken before?

A. Never been through this before, no.

Q. Well, you're doing great so far.

Please respond verbally to all of my questions. The nod of the head obviously can be picked up by the videographer, but the court reporter can't get that down. So you need to respond verbally. Understood?

A. Okay.

Q. If you need to take a break at some point, let me know. We can do that.

A. Okay.

Q. And if any questions are unclear, please let me know. And I'll try to restate it to make the question clear. Otherwise, I'll assume that you understood my question.

A. Okay.

Q. Agreed?

Okay. Let me hand you what we've marked as Exhibit 1075, and would you identify what Exhibit 1075 is for the record.

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themselves and who they represent.

MR. PARKER: Joseph Parker, from Taft, Stettinius & Hollister, counsel for plaintiff, Duramed.

MR. DOBIE: Gordon Dobie, for the defendant, Wyeth.

VIDEOGRAPHER: And will the court reporter please swear in the witness.

Whereupon --

PAUL SIMON, the Witness, called for examination by the Defendant, was duly sworn by the notary public and testified as follows:

EXAMINATION BY COUNSEL FOR DEFENDANT

BY MR. DOBIE:

Q. Would you please state your full name for the record?

A. Paul O. Simon --

Q. Mr. Simon --

A. -- S-i-m-o-n.

Q. -- as you probably heard, I'll be asking you a series of questions here today.

A. This is my rebuttal report.

MR. DOBIE: And let me hand you -- why don't we mark this as 1076.

(Defendant's Exhibit Number 1076 was marked for identification.)

BY MR. DOBIE:

Q. What is 1076, exhibit?

A. This is my resume.

Q. Mr. Simon, what I'd like to do here today is ask you some questions about your rebuttal report, Exhibit 1075.

And before we get into that in a lot of detail, I'd like to visit with you about your background if I could.

A. Yes, sir.

Q. And let me ask you first, in terms of your experience as an expert witness: Have you ever been retained by anyone to serve as an expert witness in any case?

A. No.

Q. How did you come to be retained as an expert witness for Duramed in this case?

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1 A. I got a phone call from Carolyn Courville,  
2 who got my name from someone else as someone who had  
3 considerable experience and was available to do  
4 this.

5 She called me on the phone. We had a  
6 discussion.

7 Q. Who did she say that she got your name  
8 from?

9 A. Ed Thwaite.

10 Q. And who is Mr. Thwaite?

11 A. Ed Thwaite is a -- is another consultant.

12 Q. And was Mr. Thwaite working with Duramed  
13 to your understanding? Or...

14 A. I don't believe so.

15 Q. And what did Ms. Courville tell you about  
16 the case in that initial phone call?

17 A. She just basically asked me if I was  
18 familiar with the actions that were taken with  
19 Duramed and Wyeth-Ayerst. At which point I said,  
20 "No, I was not terribly familiar."

21 She asked me to send her a resume so  
22 that she could look at it and then have further

1 Q. And tell me what you recall about that  
2 initial meeting.

3 A. Basically, it was -- she had provided me  
4 some materials that were relevant to the case.

5 She asked me -- and clarified for me  
6 that I was going to be doing a rebuttal.

7 At this point when I had met her, I  
8 had already seen Dr. Kolassa's report. I had made  
9 some notes, and I met with her.

10 She clarified what it was that I was,  
11 you know, being retained to do; and that was to look  
12 at it, provide honest opinions -- good or bad --  
13 with regard to the report.

14 And that was basically it.

15 Q. So did you have notes and things? Had you  
16 written on Dr. Kolassa's report?

17 A. I had written on -- yes.

18 Q. And you said "good or bad." Was there  
19 anything good in Dr. Kolassa's report?

20 A. Yes.

21 Q. Things that you agreed with?

22 A. Yes.

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1 discussions, which she did.

2 Q. When was that first conversation?

3 A. Oh, my gosh. I'm going to say July.

4 Q. All right. So --

5 A. I'm guessing.

6 Q. Well, look at your report -- because  
7 that's got a date on it, doesn't it? -- Exhibit  
8 1075.

9 A. Of when she called me?

10 Q. Well, you got a date of your report,  
11 September 24, 2002.

12 A. Correct.

13 Q. When in relation to that did she call you?

14 A. I think it was in July.

15 Q. July? And at that point, did you have a  
16 report from Dr. Kolassa that she was asking you to  
17 respond to?

18 A. No.

19 Q. Did you meet with Ms. Courville?

20 A. Yes.

21 Q. Where did you meet with her?

22 A. In Houston, Texas.

1 Q. What did you agree with?

2 A. Specifically, I agreed with his premise  
3 that the sales force is the most important tool that  
4 a company has in marketing a pharmaceutical product.

5 Q. Anything else?

6 A. Not that comes to mind.

7 Q. And is it your experience, based upon  
8 years in the pharmaceutical arena, that the sales  
9 force is the most important thing in marketing a  
10 product?

11 A. Definitely.

12 Q. And what companies have you worked at  
13 where you've found that to be true?

14 A. Well, I've worked at Hoffmann-LaRoche and  
15 started in sales. So I guess you might even say  
16 that I had a bit of sales experience.

17 Moved into marketing position at  
18 Roche. Worked at Bristol Myers, where I believe the  
19 same was still true there.

20 At Teva Pharmaceuticals they have  
21 sayings that, you know, nothing happens until a sale  
22 is made; and that's pretty much, you know, the kind

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1 of thing that's true in the pharmaceutical industry.  
 2 We have to -- there has to be a  
 3 conduit between the manufacturer and the customer --  
 4 in this case, the individual who writes the  
 5 prescription.  
 6 And the sales rep is the face of the  
 7 company to the physician.  
 8 So I believe that that's true anytime  
 9 that you're going to be doing detailing or selling  
 10 branded pharmaceuticals to physicians.  
 11 Q. So this rule of thumb that nothing happens  
 12 until somebody makes a sales call on a physician --  
 13 A. Well, I wouldn't call it a "rule of  
 14 thumb"; and perhaps I shouldn't have even gone  
 15 there.  
 16 The idea, though, is that I truly  
 17 believe that the pharmaceutical representative --  
 18 when you're dealing with pharmaceuticals, the  
 19 physician is the customer. And the pharmaceutical  
 20 representative is the face of the company with the  
 21 doctor.  
 22 That's the important issue.

1 Q. All right. You mentioned  
 2 Hoffmann-LaRoche. Let's walk through your  
 3 experience if we could.  
 4 First, on the educational side, you  
 5 have a B.S. degree in Pharmacy from Ohio Northern?  
 6 A. Yes.  
 7 Q. And are you a registered licensed  
 8 pharmacist in Ohio, Pennsylvania, and Florida?  
 9 A. I am a -- yes.  
 10 My license is inactive in Florida and  
 11 in Pennsylvania. Right now I just keep my home  
 12 license active; but I am licensed -- and I did take  
 13 the boards in Florida, yes.  
 14 Q. And you graduated from Ohio Northern  
 15 University in -- what? -- about 1974?  
 16 A. '74, yes.  
 17 Q. '74. And you went to Hoffmann-LaRoche, I  
 18 see, in 1976. What did you do between the time that  
 19 you graduated in '74 --  
 20 A. I worked in pharmacy.  
 21 Q. What pharmacy?  
 22 A. Oh, I worked in a couple of different

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1 Q. Anything else that you can think of in  
 2 Dr. Kolassa's report that you agree with?  
 3 A. Not specifically.  
 4 Q. How many hours have you spent working and  
 5 analyzing the facts in this case?  
 6 A. Maybe 200.  
 7 Q. And what are you being paid per hour for  
 8 your time?  
 9 A. \$250 per hour.  
 10 Q. Now, at the time that you prepared your  
 11 report that we've marked as Exhibit 1075, had you  
 12 reviewed documents from Duramed --  
 13 A. Um-hum. Yes.  
 14 Q. -- documents from Wyeth?  
 15 You had reviewed various documents  
 16 and exhibits --  
 17 A. Yes.  
 18 Q. -- in connection with the case?  
 19 And are there additional documents  
 20 that you looked at after you had prepared your  
 21 report?  
 22 A. Not that I can remember.

1 retail settings. I also did relief work in  
 2 hospitals.  
 3 You also have to do an internship,  
 4 something to the tune of a thousand hours, before  
 5 you can even get your license. I did that in  
 6 Bellefontaine, Ohio.  
 7 My pharmacy experience, retail  
 8 pharmacy experience, was principally in Ohio and  
 9 Florida.  
 10 Q. When did you have pharmacy experience in  
 11 Florida, what years was that?  
 12 A. I think I moved there in '75.  
 13 Q. So until when?  
 14 A. Till the end of '76.  
 15 So for about a year and a half.  
 16 Q. Have you worked as a pharmacist at any  
 17 time since 1976?  
 18 A. No, no.  
 19 Q. So the last time you would have filled a  
 20 prescription is 1976?  
 21 A. Probably. I would say, most likely, yes.  
 22 I was in the service for a while, in

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1 the army, and stationed at Fort Sam Houston, where I  
2 did some pharmacy work and ran their manufacturing  
3 line.

4 Q. When was that?

5 A. Somewhere around 1976.

6 Q. So I've got you at Hoffmann-LaRoche in  
7 Nutley, New Jersey -- according to your resume -- in  
8 1976.

9 A. No, you don't.

10 I started at Hoffmann-LaRoche in 1976  
11 as a sales rep; and my sales territory was Boca  
12 Raton, Florida.

13 Q. Understood.

14 Explain for me, if you would, your  
15 career with the army.

16 A. I was a reserve army. I started out in  
17 1970 as a reservist. I was in a direct support  
18 unit.

19 When I went to pharmacy school -- in  
20 '71 I believe I started pharmacy school -- I  
21 transferred over to a heavy-equipment division in  
22 Lima, Ohio, where we did such things, frankly, as --

1 Q. So that's the reason for the overlap you  
2 talk about in your resume.

3 You've got 1976 at Hoffmann-LaRoche.  
4 So you would have been a reservist, during that same  
5 time period, in the army?

6 A. Exactly.

7 And in the reserves, it's just  
8 like -- you know, you do a weekend a month and you  
9 do a summer camp in the summer for two weeks.

10 Q. Understood.

11 Just a cautionary note: We're  
12 getting to the point where many times you and I are  
13 almost talking over each other. You got to make  
14 sure you let me finish the question before you begin  
15 to respond.

16 A. Okay.

17 Q. It feels like a normal conversation; but  
18 it's different, because she's got to take everything  
19 down.

20 A. I'm sorry.

21 Q. All right. So in 1976 you go to  
22 Hoffman-LaRoche; and at that time period -- you

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1 we did community things, like build ponds and things  
2 like that for Future Farmers of America and  
3 children's groups.

4 And you got to imagine: We're in the  
5 Midwest. So there's a lot of things like that.

6 We also did things like diverting  
7 rivers and things like that for the Army Corps of  
8 Engineers.

9 I did that until I got my pharmacy  
10 degree, at which time I moved back to the Cleveland  
11 area.

12 During that time I was doing retail  
13 pharmacy; and they had a hospital unit in Akron,  
14 Ohio, which I joined in the medical corps and did  
15 not accept an officer's commission or anything like  
16 that, because I only had about two more years or so  
17 before I was going to be getting out of the  
18 service -- but stayed in that medical unit.

19 We went to Fort Sam Houston. And,  
20 you know, that's the kind of thing, every year --  
21 every summer you have to go for two weeks in order  
22 to fulfill your responsibility.

1 mentioned before you were on the sales side?

2 A. Correct.

3 Q. And -- oh, actually, let me back up.

4 During the time period when you were  
5 a pharmacist -- 1974 through 1976, working as a  
6 pharmacist -- is it true that --

7 A. You know -- I'm going to interrupt you  
8 again. I apologize. But it was a question you  
9 asked me earlier about the last time I filled a  
10 prescription.

11 Q. Yes.

12 A. While I was working, I did do some relief  
13 pharmacy work in Florida while I was a sales rep.

14 Q. So when would that have been?

15 A. I'm trying to think.

16 That was probably somewhere around  
17 '78 to '80, '81, where I worked outside my  
18 territory.

19 You're not allowed to work in your  
20 territory, obviously -- but where I worked outside  
21 my territory, filling prescriptions in a retail  
22 environment, in Florida, while I was a sales rep at

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1 Hoffmann-LaRoche.  
 2 Q. When you were working as a pharmacist  
 3 during this time period, '74 through some period  
 4 maybe even in the early '80s, were most  
 5 prescriptions paid for by patients out of pocket,  
 6 cash?  
 7 A. It depends on where you work.  
 8 When I worked in Akron, because of  
 9 the rubber companies -- Goodyear, etc. -- something  
 10 in the neighborhood of 80 percent of our  
 11 prescriptions were filled by cards like PCS.  
 12 At that time we had Medimet, which  
 13 ended up being bought by Medco.  
 14 When I worked in Florida, it was a  
 15 lot less of the cards used to fill prescriptions.  
 16 Q. Do you know what percentage of the  
 17 population had insurance for prescription products  
 18 during the period when you were working as a  
 19 pharmacist?  
 20 A. At that point?  
 21 I honestly couldn't tell you if I  
 22 had -- I mean, I could guess.

1 country?  
 2 A. In Florida.  
 3 Q. Your resume also talks about taking --  
 4 turning a \$12,000 clinical lab territory to reach \$1  
 5 million in sales.  
 6 Is that the blood-testing services  
 7 that Hoffmann-LaRoche would do?  
 8 A. Yes, it is.  
 9 Q. Now, during this time period when you were  
 10 at Hoffmann-LaRoche, did you have any responsibility  
 11 for calling on managed-care customers?  
 12 A. At Roche we didn't really have a lot of  
 13 HMOs or managed-care customers at the time that I  
 14 was selling. So I did not call on managed care at  
 15 Roche.  
 16 I'm trying to think. We had one  
 17 managed-care customer, and that was it.  
 18 However, I did call on hospitals,  
 19 etc.; and those really were kind of the beginning of  
 20 managed care for us.  
 21 Q. So a hospital would have, many times, a  
 22 closed formulary; and you would be calling on a

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1 But it would be -- in the Akron area,  
 2 it could have easily been 80 percent. In the  
 3 Florida area, I honestly don't know.  
 4 Q. All right. Hoffmann-LaRoche, you're there  
 5 as a sales rep -- pharmaceutical and clinical labs,  
 6 your resume states.  
 7 Now, that part of Hoffmann-LaRoche,  
 8 was that the -- were you involved in selling  
 9 pharmaceutical products during that same period?  
 10 A. Yes.  
 11 Q. Was that blood-testing services?  
 12 A. I sold that as well.  
 13 Q. What pharmaceutical products did you sell?  
 14 A. Valium, Dalmane, Librax, Bactrim,  
 15 Larotid -- which is amoxicillin -- Trimpep, Zantac.  
 16 I'm sure there are more that I'm not  
 17 remembering. But...  
 18 Q. So your responsibilities, when you were a  
 19 sales rep, were to sell a whole host of different  
 20 pharmaceutical products to whom? Doctors?  
 21 A. Yes.  
 22 Q. And the doctors were in what part of the

1 hospital to present the Hoffmann-LaRoche products?  
 2 A. Exactly.  
 3 Q. You said that --  
 4 A. Now, just so that you know:  
 5 There were managed-care clinics in my  
 6 territory, which I would call on; but that was not  
 7 the home office -- if that's what you're referring  
 8 to.  
 9 Q. What are the managed-care clinics you're  
 10 saying you were --  
 11 A. Oh, my gosh. I can't remember any of  
 12 those names.  
 13 Q. Who did you report to at Hoffmann-LaRoche  
 14 when you were on the sales side?  
 15 A. I had two bosses: One was Bill Mrazek,  
 16 who retired while I was there; and the other was Pat  
 17 Ceralo.  
 18 Q. You mentioned that there was one  
 19 managed-care account that Hoffmann-LaRoche had.  
 20 Did Hoffmann-LaRoche have a team that  
 21 called on that account?  
 22 A. Where do I mention that?

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1 Q. That's what you just said a moment ago.  
2 A. No.  
3 Q. Did I misunderstand?  
4 A. There are -- there were managed-care  
5 accounts. I didn't call on corporate headquarters.  
6 Q. Do you know if anybody at Hoffmann-LaRoche  
7 did?  
8 A. Yes.  
9 Q. Was there a department that was  
10 responsible for that?  
11 A. At the time there wasn't a department.  
12 There were individuals that were  
13 assigned those responsibilities, and they basically  
14 fell upon the individual whose territory the  
15 managed-care company was in.  
16 There was an individual in Miami. I  
17 do not remember the name of the managed-care company  
18 in Miami, but the sales rep that called on them was  
19 Les Wachman. And I'm sure he retired before I even  
20 got promoted.  
21 Q. All right. And at Hoffmann you say that  
22 you developed the Zantac forecast used by senior

1 individuals that would be involved between Glaxo and  
2 Hoffmann-LaRoche in detailing physicians?  
3 A. It was looking at sales trends and  
4 providing -- let me clarify.  
5 Your question is about, how did I  
6 forecast?  
7 Q. Yes, sir.  
8 A. Okay. It was looking at the trends that  
9 were occurring in the marketplace and what were the  
10 anticipated sales that we would be getting for Years  
11 2, 3, and 4.  
12 Q. When you were forecasting what sales that  
13 Hoffmann-LaRoche might be getting, did you look at  
14 how many folks would be involved in detailing?  
15 A. Absolutely.  
16 Q. And why did you do that?  
17 A. Because you want to know what kind of a  
18 sales resource is going to be applied to the  
19 product.  
20 Q. Were there different forecasts, depending  
21 upon how many sales folks were involved?  
22 A. No. There was no need to do that, because

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1 management to negotiate marketing goals with Glaxo  
2 assigned as a core team member.  
3 A. Correct.  
4 Q. And was that when you became a senior  
5 analyst?  
6 A. That was within three months of coming in  
7 as a market research analyst.  
8 Q. Zantac is a product that's a stomach  
9 medicine; right?  
10 A. Correct.  
11 Q. And it competed with products like  
12 Tagamet?  
13 A. Very good. Yes.  
14 Q. And the product was developed by  
15 Hoffmann-LaRoche -- by Glaxo?  
16 A. Yes.  
17 Q. And so, Glaxo came to Hoffmann-LaRoche to  
18 look for assistance with having a sales force?  
19 A. Yes.  
20 Q. And consistent with, I guess, what you  
21 told me before -- was part of what you were doing  
22 when you were forecasting looking at how many

1 you had one -- one sales force already dedicated to  
2 the product. Why would you look at various  
3 scenarios?  
4 Q. Understood.  
5 So there was already -- Glaxo already  
6 had a sales force, and then they were adding the  
7 Hoffmann-LaRoche sales force?  
8 A. Glaxo had a sales force, and  
9 Hoffmann-LaRoche provided or had a deal with Glaxo  
10 that they would promote the product with so many  
11 details a year; and I have no idea what that numbers  
12 was.  
13 But they would provide detailing  
14 efforts and get paid based on -- and this is really  
15 confidential information for the company, which I  
16 was not certainly privy to -- but I was led to  
17 believe it was based on, you know, a percentage of  
18 the sales.  
19 Q. All right. And your resume also states  
20 that you spearheaded a four-person task force that  
21 developed a forecasting system, resulting in an \$8  
22 million inventory reduction.

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1 What type of forecasting system was  
2 that?  
3 A. There are several techniques used to  
4 forecast.  
5 It's a production forecasting system.  
6 Is that what --  
7 Q. So that was production?  
8 A. Right.  
9 Q. And then you've got: "Managed in-house  
10 research agency that coordinated and fielded all  
11 primary marketing research activities and reduced  
12 supplier expenses by 40%."  
13 Is that on the production side?  
14 A. No; that's on the marketing side.  
15 Q. Tell me about that, if you would.  
16 A. Typically, in marketing research --  
17 marketing research, in the pharmaceutical industry,  
18 is -- has lots of sources of secondary data on what  
19 physicians are doing and regular prescriptions,  
20 where prescriptions are going -- unlike the consumer  
21 packaged-goods industry.  
22 However, there is a considerable

1 A. IMS. Scott Levin at the time. There was  
2 PDS, NDC.  
3 Now, it's -- VariSpan has pulled  
4 together a lot of the assets from other companies.  
5 Q. And what type of information don't they  
6 capture?  
7 A. Oh, that's a tough question, what they  
8 don't capture.  
9 I can tell you what they do capture.  
10 They capture the prescription  
11 information, what doctors are writing -- because  
12 they actually get a view of the prescriptions.  
13 Companies like PCS, which previously  
14 owned a company called "PDS" -- and that's how they  
15 got their start, looking at and developing what's  
16 today called the "source database," that actually  
17 looks at prescription data. And they will go so far  
18 as to tell you what the average prescription refill  
19 rate looks like, things like that.  
20 So you get a lot of the behavioral  
21 kinds of things that are occurring in the market.  
22 What you miss are a lot of the

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1 amount of information that's not captured by these  
2 secondary data sources which requires you to go out  
3 and do the research itself. Hence, primary  
4 research -- for example, doing things like  
5 positioning studies or looking at sales aids, if you  
6 will, and meeting with doctors and asking them and  
7 getting opinions from physicians on the value of the  
8 messages, etc., that are provided in the sales aids.  
9 Those are the kinds of things that  
10 are more economically done at a convention or  
11 something like that, where you've got 10 OBs. You  
12 can, you know, give them \$500 or something like that  
13 to come back and look at this or to go to a hotel  
14 room and go through the market research.  
15 We did this in-house and formed our  
16 own agency rather than paying someone else to go  
17 outside and get those services done.  
18 Q. You said that lots of data is not captured  
19 by these data companies, data services?  
20 A. Correct.  
21 Q. What are the companies you're talking  
22 about there?

1 attitudinal things, like: Why is a doctor doing  
2 what a doctor is doing?  
3 Those kinds of questions aren't  
4 captured by the audits.  
5 Q. When you were manager of marketing  
6 research and information planning, who did you  
7 report to?  
8 A. I had two bosses: I reported to the head  
9 of marketing research. I also reported --  
10 Q. What was his --  
11 A. Tom Silberg, S-i-l-b-e-r-g.  
12 I also reported to Dr. Bruce Medd,  
13 M-e-d-d. He was a physician and head of the  
14 professional services -- all the professional, which  
15 included marketing services, medical affairs, all  
16 those groups.  
17 Q. And why did you leave Hoffmann-LaRoche in  
18 1987?  
19 A. The biggest reason was to move back to the  
20 Midwest, and I was being recruited to come to  
21 Evansville to do something similar in nature to what  
22 I had done at Hoffmann-LaRoche.

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1 Q. 1987, Hoffmann-LaRoche had some hard times  
2 and everything. There were some layoffs, I think,  
3 in the company.  
4 A. Yes, there were.  
5 Q. Were you part of any head-force reduction?  
6 A. I was there when it happened; but, no.  
7 Actually, that was -- that was a  
8 rough time for everybody. But I was not caught up  
9 in...  
10 Q. Bristol-Myers was your next company from  
11 1987 to 1993. And there, you worked as the manager  
12 of information planning and the manager of worldwide  
13 marketing research for the nutritional side of the  
14 Bristol-Myers Squibb company; correct?  
15 A. Correct.  
16 Q. And that would include infant formula?  
17 A. Correct.  
18 Q. What other products?  
19 A. Well, I also had women's health-care  
20 products --  
21 Q. What --  
22 A. -- until we purchased Squibb.

1 worldwide marketing research.  
2 And -- but I still maintained  
3 activity for both managed care and women's  
4 health-care products on the pharmaceutical side.  
5 Let me further clarify:  
6 There were seven divisions of  
7 Bristol-Myers or Mead-Johnson at the time. Only two  
8 of which were nutritional: Adult and infant  
9 nutritional divisions.  
10 So in order for it to be handled by  
11 one person, you couldn't dump five divisions on  
12 another individual to have responsibility. So when  
13 they split it up, I got those as well.  
14 Q. So -- on your resume it says manager of  
15 information planning. It says "United States  
16 Pharmaceutical and Nutritional Group."  
17 A. Correct.  
18 Q. And then when you were manager of  
19 worldwide market research, which is the '89 through  
20 '93, it says "Mead-Johnson Nutritionals."  
21 A. It is nutritionals, but I also had those.  
22 Q. You also had the Mead-Johnson women's

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1 Once Squibb was bought by  
2 Bristol-Myers, they separated the businesses and  
3 moved all the pharmaceutical divisions to New  
4 Jersey.  
5 But prior to that time, the  
6 Mead-Johnson Women's Healthcare Group also was -- I  
7 also had that responsibility.  
8 Q. You had -- and let me make sure, first, I  
9 understand -- you had responsibility for information  
10 planning or worldwide market research for the  
11 Mead-Johnson products?  
12 A. Both.  
13 The -- and let me clarify the  
14 question, if I can.  
15 Those were two different jobs --  
16 Q. Understood.  
17 A. -- at two different periods of time.  
18 I did the information-planning piece.  
19 That was why I came to the company.  
20 When the information planning and the  
21 strategic plan was done, they split the company up.  
22 At which point I was moved in to be responsible for

1 products?  
2 A. For a short period of time. Like I say,  
3 until they moved to -- what is it? -- Princeton, New  
4 Jersey, yes.  
5 I'm going to say it was probably a  
6 year, maybe less than a year. I went through one  
7 cycle, one strategic planning cycle, with the  
8 women's health-care products.  
9 Q. And what were the Mead-Johnson's women's  
10 health-care products that you were involved in?  
11 A. Estrace. They had an ovulation-control  
12 product, which -- frankly, the name escapes me.  
13 And I had an analyst -- the major  
14 role that I would play with that group was to  
15 participate in major -- you know, in big-picture  
16 strategic or tactical decisions.  
17 So when the promotional plans were  
18 being presented for products, I was there more as an  
19 individual to review what was going on -- what was  
20 happening, what they were planning to do with the  
21 brands -- and ask questions, than anything else.  
22 Q. Any other Mead-Johnson women's products

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1 that you were involved in?

2 A. No.

3 Q. At the time that you were at Bristol-Myers

4 Squibb, did you ever have occasion to call on

5 managed-care companies?

6 A. No.

7 Q. Did you have occasion to call upon doctors

8 to promote any of the Bristol-Myers Squibb products?

9 A. To personally make sales calls, are you

10 asking?

11 Q. Yes, sir.

12 A. No.

13 Q. Did you ever oversee a department that was

14 responsible for making sales calls on doctors?

15 A. No, I did not.

16 Q. Did you oversee any department that had

17 responsibility for calling on managed-care

18 companies?

19 A. That depends how you mean the question.

20 I didn't physically make calls to

21 managed-care customers.

22 Q. Okay. I understand -- you told me that

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1 already.

2 I'm asking whether you managed any

3 department that called on managed-care customers.

4 A. That called on them, no.

5 Q. What your resume says is that you were

6 involved in primary market research for managed

7 health care.

8 What does that mean?

9 A. "Managed health care" -- I'm trying to

10 find a way to explain this.

11 At Bristol-Myers we had, as I said,

12 like seven different divisions that were involved in

13 managed care.

14 The managed-care group was a

15 centralized group, calling on the large customers --

16 the HMOs, the PPOs, etc. And we had to look for

17 ways to promote products into those customers.

18 I would be involved in discussions --

19 and again, at the strategic level, in decisions and

20 discussions -- about those customers in how to work

21 with them, how to make our basket, if you will, more

22 attractive.

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1 Q. What were the products that you were

2 trying to sell to the managed care -- or the

3 managed-care department would be trying to sell into

4 these managed-care customers? These women health

5 products you're talking about?

6 A. Could be.

7 Q. Would it be the institutional products as

8 well?

9 A. Could be, yes.

10 Q. Not infant formula, though; right?

11 A. Actually, infant formula as well --

12 because we looked at managed care as being not just

13 an HMO or a PBM, but the state Medicare, Medicaid.

14 Medicare, as you know, is a big

15 purchaser of products in long-term-care facilities.

16 And there are programs for women, infant, and

17 children that are done at the state level, funded

18 with Medicaid dollars.

19 So for those, and doing -- building

20 pricing models and talking about how do you create

21 an appropriate price for -- to make sure that you

22 get these contracts -- and it was looking for things

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1 like applying shelf pressure to the drugstore shelf,

2 etc.

3 Q. What does that mean, "shelf pressure"?

4 A. Imagine, if you will, that you've got

5 three foot of shelf space allocated by a drugstore

6 for infant formula. If you own two and a half feet

7 of it, that's what I'm calling "shelf pressure."

8 You know, whatever your space is, you

9 draw attention towards your products.

10 Q. So would Bristol-Myers Squibb try to get

11 shelf space within various pharmacies or other

12 retail outlets for their products?

13 A. Absolutely. That's -- every -- all

14 consumer companies work that way.

15 Q. Do they sign contracts to try to get that

16 shelf space?

17 A. Yes.

18 Q. Were you involved in that at all?

19 A. In the contracting of -- for shelf space?

20 No, not at all.

21 Q. But were you in meetings and things where

22 that was discussed as part of the strategy?

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1 A. No, not at -- no.

2 Q. So you don't know whether or not

3 Bristol-Myers sought arrangements with various

4 retailers to have its Mead-Johnson products and,

5 let's say, a preferred shelf position within

6 particular retailers?

7 A. I don't understand the question.

8 Q. You don't know whether or not

9 Bristol-Myers entered into agreements with various

10 retailers that had to do with what shelf space they

11 would be provided?

12 A. I don't have -- I have not personally seen

13 the contracts; but I believe that that was done,

14 yes.

15 Q. All right.

16 A. Sorry for that.

17 Q. Estrace, you mentioned before, was a

18 Bristol-Myers product -- E-s-t-r-a-c-e. That's an

19 estrogen-replacement therapy?

20 A. Yes.

21 Q. And is that a generic product?

22 A. I believe it's generic now. Generically

1 managed-care sales force?

2 A. Four.

3 Q. And when you were presenting Teva

4 products, did you personally call on managed care --

5 A. With my account managers, yes.

6 I attended meetings. I also attended

7 conventions and things like that, yes.

8 Q. All right. And with generic products --

9 with the Teva products, when you were trying to

10 get -- or get in to see managed-care customers --

11 the products don't go through a P&T review; do they?

12 A. Typically, no.

13 Q. The products themselves are assumed to be

14 bioequivalent to the patented product?

15 A. Typically, yes.

16 But that's not necessarily the way

17 that people look at the products.

18 Q. Well, let me ask you this:

19 The negotiations that would take

20 place with Teva, did any of them -- any of the

21 managed-care negotiations that you were involved

22 in -- when people are looking at those products, is

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1 available.

2 "Estrace" still is a brand.

3 Q. It was generically available back at the

4 time that you were at Bristol-Myers Squibb?

5 A. Not -- I don't think so.

6 Q. Do you know whether Bristol-Myers Squibb

7 had any contracts that covered Estrace with

8 managed-care organizations?

9 A. Do not know.

10 Q. The next thing I see on your resume is

11 Teva Company, formerly "Lemmon Company," in

12 Pennsylvania.

13 You were there from 1993 to 1997?

14 A. Yes.

15 Q. And is Teva largely a generic drug

16 company?

17 A. Largely it is, yes.

18 Q. And what did you do at Teva?

19 A. At Teva I was responsible for marketing.

20 I also was responsible for the managed-care sales

21 force.

22 Q. How many people were on the Teva

1 it basically they're looking at it from a price

2 standpoint?

3 A. Yes and no. No; I won't say that that's

4 true.

5 When -- if you are a commodity

6 product where you are in the marketplace with, let's

7 say, 13 other products -- like Captopril -- when

8 Captopril went generic, there were 13 different

9 generic companies in the marketplace. And it truly

10 was a commodity.

11 When you go out as a first-alone --

12 let's say, for example, when Andrex goes out with a

13 single product like Prilosec, and they have six

14 months of exclusivity, it's not treated like you

15 would treat a commodity product. And you don't talk

16 to managed care in the same way that you would with

17 a commodity product.

18 Q. Well, one of the things if -- you've got

19 in your example there, if you've got the first

20 generic product that gets approved, in that

21 situation you do have exclusivity for six months;

22 right?

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1 A. Basically, yes.

2 Q. And you need to tell --

3 A. At least six months.

4 Q. At least six months.

5 And you need to tell managed care

6 that the product is out there; right?

7 A. Yes.

8 Q. And you also have a certain amount of

9 leverage, because there are only two products during

10 that time point; right?

11 A. Correct.

12 Q. And did you, when you were at Teva, have

13 any products that were the first product to be

14 approved by the FDA?

15 A. Several.

16 Q. Several.

17 What were those products?

18 A. Two that come to mind are Clonazepam and

19 Cardizem --

20 Q. And so --

21 A. -- which is Diltiazem.

22 Q. -- were those products -- let's take the

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1 Cardizem example.

2 If Teva was the first generic

3 product, you would approach various managed-care

4 companies and suggest putting the Teva Cardizem

5 product on the formulary?

6 A. Um-hum. Correct.

7 Q. And here's what I'm getting at:

8 Doesn't it just work as a matter of

9 state law in many places --

10 A. Absolutely not.

11 Q. Wait, wait, wait. You got to let me

12 finish the question.

13 A. I'm sorry.

14 Q. Okay. And you can educate all of us.

15 But the question I had is:

16 Doesn't it work, as a matter of state

17 law or just as a matter of practice, generally, that

18 if somebody would write a prescription for, let's

19 say, a Cardizem -- and unless they, you know, check

20 that box that says, you know, you can't substitute

21 for a generic -- that the product just gets filled

22 with the generic?

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1 A. No.

2 Q. Why not?

3 A. Take New Jersey, for example.

4 New Jersey has a formulary committee.

5 Unless your product is approved by New Jersey, you

6 aren't allowed to sell that product in New Jersey.

7 Q. So --

8 A. No matter -- I mean, even if there are 13

9 generics out there, you can't substitute.

10 Q. So generic products have to get approved

11 by P&T committees in various states?

12 A. There's -- there are machinations that you

13 need to go through in order to get approvals. And I

14 would use a different example of a product.

15 For example, use a -- use a product

16 like Carbamazepine.

17 Are you familiar with Carbamazepine?

18 Q. I'm not.

19 A. Carbamazepine is -- brand name, Tegretol.

20 Still, a major part of the

21 marketplace is brand because of the nature of the

22 drug.

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1 Even though there are two or three

2 generic companies out there, you still need to go in

3 and promote your product.

4 Q. Can you think of any examples at Teva

5 where managed care didn't cover a first-approved

6 generic product?

7 A. Where managed care didn't cover?

8 Q. Yes.

9 A. I don't understand your question, because

10 "managed care" is not one company. It's a bunch of

11 little companies.

12 I'll give you a great example.

13 I launched Warfarin when I was at

14 Taro. Medco didn't reimburse for generic; they only

15 reimbursed for the brand.

16 And by the way, Barr had launched

17 Warfarin two years earlier.

18 Q. Right.

19 And Barr -- that's what I was --

20 that's sort of what I was wondering, is: I assume

21 that Medco reimbursed the Barr Warfarin sodium --

22 A. (Witness shakes head.)

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1 Q. No?

2 You got to respond, so she can --

3 A. No.

4 Finish the question. I'm sorry. I

5 shouldn't have done that.

6 Q. Yes. What I'm just trying to understand

7 is:

8 What you're saying is, is that there

9 are many instances where there's a product that's

10 patented; and managed-care companies will decide not

11 to reimburse for a generic product that is the first

12 approved generic product in that particular

13 category?

14 A. I'm saying that that does occur, yes.

15 Q. And you gave us this one example with

16 Warfarin.

17 Can you think of any others?

18 A. I think that there's -- there's more to it

19 than just looking at what managed care will or will

20 not reimburse for.

21 There is -- there are other things

22 involved than just that.

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1 Q. Well --

2 A. Dilantin might be another excellent case.

3 Q. All right. So there's examples where that

4 happened; but would you agree with me that,

5 generally speaking, managed-care companies will

6 reimburse for generic products?

7 A. Generally speaking, I will agree with

8 that, yes.

9 Q. And generally speaking, the discussions

10 and negotiations with managed-care companies about

11 generics typically relate to issues of price,

12 because the products aren't reviewed at the P&T

13 level; right?

14 A. No, I don't agree with that.

15 Managed care -- how do I say this?

16 Managed care doesn't get into price.

17 Managed care looks at what it's reimbursing for the

18 product; and they may set what's known as a "maximum

19 allowable cost" or something like that on a generic

20 product. They don't get into whose generic is going

21 to be used.

22 Q. So they don't -- that's what I'm

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1 wondering.

2 A. Your discussions with managed care -- and

3 I'll give you an example -- like, Pharmacy Gold --

4 would be on quality of the product.

5 MR. DOBIE: Can you read that -- not

6 that answer, the answer before -- just read

7 that back for me.

8 I want to make sure I understood

9 Mr. Simon's testimony.

10 (Whereupon, at this time the

11 referred-to answer was read by the

12 reporter.)

13 THE WITNESS: And let me clarify

14 that.

15 They don't typically get involved in

16 whose product is going to be used.

17 BY MR. DOBIE:

18 Q. So when you say they don't typically look

19 at price, but they may set a maximum allowable cost,

20 what does that mean?

21 A. Are you familiar with a federal upper

22 limit?

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1 Q. You got to explain it for the record.

2 The maximum allowable cost that they

3 may set, what does that mean?

4 A. The -- when generics come to market, the

5 price of the products are typically lower than the

6 price of the brands.

7 The AWP, the Average Wholesale Price,

8 may be only 10 percent below the price of the brand;

9 but the actual selling price will be considerably

10 lower than that.

11 When a generic first comes to

12 marketplace, a reimbursement formula -- and I cannot

13 tell you what everybody's reimbursement formula

14 is -- but a reimbursement formula might be based on

15 the AWP, until the product is generally accepted and

16 available in the marketplace.

17 Once the product is generally

18 available in the marketplace, the benefit managers

19 will typically go out, and try and find out what is

20 the actual price or what, typically, are pharmacies

21 paying for the product?

22 And then they will set that, or some

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1 number calculated off of that, as a "maximum  
2 allowable cost."  
3 Any prescription that is filled after  
4 that time will be based on that "maximum allowable  
5 cost" plus a dispensing fee.

6 Q. So with generic products, once they're out  
7 there for a while this "maximum allowable cost" that  
8 you're talking about is something that's based upon  
9 a review of the marketplace and what people are  
10 actually selling the product for?

11 A. Say that again.

12 Q. I'm going to strike the question. I think  
13 I understood.

14 What did you mean when you said that  
15 managed care doesn't generally get concerned with  
16 what product is used?

17 A. Managed-care companies look at -- for --  
18 as a general rule -- and this is not all of them, by  
19 the way -- and I can give you examples of other  
20 companies that haven't -- but as a general rule,  
21 managed-care companies don't want to dictate that  
22 Wal-Mart or any particular customer is going to use

1 think I understand your question is just those going  
2 through retail. So for retail, they typically don't  
3 have a lot of those.

4 Q. I just want to make sure I understand  
5 this.

6 The generic companies will have  
7 contracts that cover the closed situations like you  
8 described, like a Kaiser -- where they actually, you  
9 know, own the hospitals and they control exactly  
10 what prescription products are given to their  
11 patients --

12 A. Um-hum.

13 Q. -- but they won't typically have contracts  
14 that tell, for example, a Medco what generic product  
15 they're going to dispense --

16 A. I'm really --

17 Q. -- when somebody -- let me just finish --  
18 when somebody goes into the Wal-Mart with a pharmacy  
19 prescription?

20 A. I'm really glad you brought that one up.

21 Yes, I would. I would very  
22 definitely have a contract with a Medco.

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1 a particular company's generic product.

2 They're going to dispense what is  
3 available in the drugstore, not -- you know, it's  
4 not going to be Teva's generic. It could be  
5 Myland's generic product.

6 Q. Okay.

7 A. And they'll reimburse the same, no matter  
8 what.

9 Q. So in light of that, this is what I'm  
10 trying to understand:

11 If that's the practice -- that you go  
12 to a Wal-Mart, and they are not concerned whether  
13 it's the Teva generic or the Barr Labs generic --  
14 what are these contracts that are being negotiated  
15 between a Teva and a managed-care company?

16 A. You don't typically have a lot of  
17 contracts -- generic companies don't typically have  
18 contracts with managed-care companies.

19 We would have contracts with  
20 managed-care companies like a Kaiser, where they're  
21 closed-wall.

22 But the ones -- and I believe -- I

1 Q. Why is that?

2 A. For two reasons -- and herein lies part of  
3 the reason with the Warfarin.

4 Because Medco has two businesses --  
5 they have the benefit-management company as well as  
6 the mail-order company -- anybody that can purchase  
7 or dispense or anyone that really buys product, per  
8 se -- hence, the mail-order business -- you sell to.

9 And oftentimes, what you'll find is  
10 that the two can be tied together when it comes to  
11 the brand.

12 Q. Do you know whether or not -- whether  
13 Duramed or Barr had a contract with Medco for  
14 Cenestin on the mail-order side of the business?

15 A. On just the mail-order side of the  
16 business?

17 Q. Yes.

18 A. I believe that they were talking to Medco,  
19 but I don't believe that they picked up a contract  
20 on the mail-order side.

21 Q. Let's go back to my -- what I was trying  
22 to ask you, as a general matter --

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1 A. I could be wrong about that. Okay?

2 Q. Let's set Medco aside. All right?

3 But I'm going back to your statement

4 that, generally, managed care doesn't care what

5 products -- what generic products are being

6 prescribed. Okay?

7 I'm trying to understand that, so

8 that we're clear here.

9 At Teva Pharmaceuticals -- all

10 right? -- are they able, generally, to contract with

11 managed-care companies so that, when somebody goes

12 into a Wal-Mart with a prescription, that the

13 product will be filled with their generic product as

14 opposed to somebody else's generic product?

15 A. The answer is: We used to be able to, but

16 I don't believe that they do today.

17 Q. And when was that true, that you used to

18 be able to do that?

19 A. We used to have a contract with a company,

20 a managed-care company, a Blue Cross Company -- Blue

21 Cross/Blue Shield -- out of Minneapolis, that would

22 actually reimburse at a higher level to the retail

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1 purchaser.

2 In other words, if a drugstore bought

3 Teva's products or Lemmon product and sold that

4 product -- by using that NDC number when they went

5 for reimbursement from Blue Cross/Blue Shield, they

6 could actually get a higher rebate back.

7 Q. The retailer would get a higher rebate

8 back?

9 A. The retailer would get a higher rebate

10 back than if they gave someone who was not an

11 approved.

12 And in this particular case, Blue

13 Cross/Blue Shield came out. They visited our

14 facilities. They went to Israel to actually inspect

15 where the manufacturing was being done.

16 Q. And then you said they're no longer doing

17 that.

18 When did they stop doing that?

19 A. I couldn't tell you.

20 Q. Did it happen while you were still there?

21 A. Oh, absolutely.

22 Q. So it would have been some point prior

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1 to --

2 A. I --

3 Q. -- '97?

4 A. It was on its way to being -- to going

5 away probably around '97 or '98.

6 Q. Is that the only contract that you're

7 aware of that was like that?

8 A. That's the only one that I was aware of.

9 It doesn't mean we weren't trying to

10 get others to do that; but, yes, that was the only

11 one.

12 Q. And why were you trying to get others to

13 sign such contracts?

14 A. Well, we -- we thought it would be great

15 if we could get, you know, improved image for

16 ourselves as being, you know, approved. It looks

17 good.

18 They've come out and inspected us;

19 and they've said, "We've got a clean bill of health.

20 We look good."

21 Q. Not only that, they would fill the

22 prescription on a preferred basis with a Teva

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1 product versus another one, I assume?

2 A. Correct.

3 Q. And did Teva give the retailer a better

4 price for the product?

5 A. No.

6 Q. Just a higher rebate?

7 A. It would just be a higher rebate from the

8 Blue Cross/Blue Shield.

9 Q. What products were covered by that?

10 All Teva products?

11 A. Yes.

12 Q. Do you know why they did away with that

13 kind of trade?

14 A. Because the retailers didn't want them

15 dictating what kind of products they would be

16 stocking. They didn't feel it was fair.

17 So they did away -- it was -- it

18 could have been a right decision.

19 Q. Are you aware of any other situation where

20 generic companies enter into contracts -- or --

21 strike that.

22 Have you been involved with any other

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1 generic pharmaceutical companies where they enter  
2 into contracts with managed-care organizations to  
3 provide for rebates or preferred positions, anything  
4 like that?

5 A. Have I been involved with any?

6 Well, here again, it depends on what  
7 you call "managed care."

8 If you're talking about "group  
9 purchasing organizations" and things like that --  
10 absolutely.

11 If you're talking about a "PBM" --  
12 then, no.

13 Q. A PBM or an HMO?

14 A. Repeat the question.

15 Q. Okay. I'm not talking about "group  
16 purchasing organizations," like a group of all  
17 hospitals together buying pharmaceuticals and trying  
18 to get the best deal. I'm talking about either an  
19 HMO or PBM.

20 Have you been involved in any other  
21 situation with any other generic products where the  
22 managed-care organizations entered into a contract,

1 sole source -- you know, first-alone, generics,  
2 etc., just those.

3 I mean, we talked to PCS for -- when  
4 we came out with the Dilitizam, twice-a-day-dosage  
5 form, to try and get them to put it on and actually  
6 do programs for it.

7 Q. So in those situations where the generic  
8 was the sole generic --

9 A. -- where you were just one or maybe even  
10 two, you would talk to them about it.

11 Or in the case of a -- what they call  
12 a "narrow therapeutic index" product, an NTI drug --  
13 such as Warfarin or any blood-thinner, or an  
14 anticonvulsant, or things like that -- you would  
15 still talk to PBMs to try and move business, yes.

16 Q. And try to get a rebate contract with  
17 them?

18 A. And try and get a rebate contract,  
19 exactly.

20 Q. Would the rebates be paid in exchange for  
21 listing you as the sole source or only generic  
22 product or one of two generics?

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1 with the generic company, that provided for some  
2 sort of a rebate or preferred position for the  
3 generic?

4 A. If you're talking, again, retail -- no.

5 If you're talking managed care, like  
6 VA, Kaiser, or those -- then, absolutely.

7 Q. All right. So the closed-formulary-type  
8 situations?

9 A. Correct.

10 Q. But not on a more traditional --

11 A. Retail, where it goes directly to the  
12 managed-care company? No.

13 Q. Okay.

14 A. Not that I can remember anyway.

15 Q. With the generic companies that you've  
16 worked with, do the generic companies enter into  
17 contracts for formulary placement?

18 A. At PBMs?

19 Q. PBMs or HMOs.

20 A. It's been a while since I've called on the  
21 PBMs.

22 Only for those products that would be

1 Was that common in your experience?

2 A. Sole source -- with managed care? No.

3 We would do sole-source contracts  
4 with -- you know, in the supply channel, but  
5 definitely not with...

6 Q. So you would have sole-source contracts  
7 with -- when you say, with a supply channel --  
8 you're talking about with wholesalers?

9 A. Yes.

10 Q. So if you're the only source of a generic  
11 product, you would give the wholesalers or the  
12 pharmaceuticals -- you got to let me finish the  
13 question.

14 A. Okay.

15 Q. -- you would give them a rebate or a  
16 better price?

17 A. No.

18 Q. How did it work?

19 A. I would not -- if I was the only person  
20 there, I would be treating my product more like a  
21 brand. I would not be giving additional discounts.

22 Q. I'm confused.

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1 I thought you said you entered into  
2 contracts with managed care -- I'm sorry, with these  
3 wholesalers.

4 What were the contracts for, then?

5 A. For products where you had 13 different  
6 competitors.

7 When you have 10 different people in  
8 there selling the same product, then -- and it is  
9 looked at as a commodity -- then you have to go and  
10 get -- you give them a price concession for a  
11 compliance concession.

12 In other words, you're the only one.  
13 Or they're guaranteeing so you much business; and  
14 you're guaranteeing them a price, a better price.

15 Q. Who is the "they" you're referring to?

16 A. The wholesaler. I'm sorry.

17 Q. Medi-Span, you were the director of market  
18 planning?

19 A. Basically. The director of marketing.

20 Q. And it says here that you were working on  
21 developing new technology products?

22 A. Yes.

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1 Q. All right. And one of the things that I  
2 took from your report was, you were looking at  
3 figuring out whether or not you could sell doctors a  
4 product that would be an up-to-date listing of  
5 formulary status?

6 A. Yes.

7 Q. And that's a product that was never  
8 launched; right?

9 A. The company was sold.

10 Q. So the answer is: The product has never  
11 been launched?

12 A. The product has never been launched.

13 Q. Are you aware of any company that has ever  
14 launched such a product?

15 A. Am I aware of any? No, I'm not.

16 I -- no, I'm not.

17 Q. Taro Pharmaceuticals, you were there from  
18 1998 through 2000, vice president of Northern  
19 America Marketing.

20 And that's a generic company, but  
21 also has Coumadin; is that right?

22 A. Yes, sir.

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1 Q. What responsibility, if any, did you have  
2 at Taro as relates to managed care?

3 A. The only involvement I had with managed  
4 care was getting them to bring an individual in to  
5 sell into managed care, as well as to help that  
6 individual to prepare a plan for how he would  
7 approach the marketplace and to present that to  
8 senior management.

9 Q. And so, he developed the plan for how to  
10 sell to managed care the Taro generic products?

11 A. He developed a plan; and he and I  
12 presented the plan to senior management, as to what  
13 products and customers we would focus on with regard  
14 to managed care.

15 Q. And what products were you selling to  
16 managed care or did you plan on selling to managed  
17 care?

18 A. Well, Taro is a -- mostly a creams and  
19 ointments company. So what we were primarily  
20 selling was creams and ointments.

21 We were just starting to become a  
22 company that was involved in solid dosage forms. We

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1 had a couple of rather good products, but those were  
2 really not the focus.

3 It was part of our focus to get these  
4 customers aware of the fact that we weren't just a  
5 creams-and-ointments company; but in the same  
6 context, when you're just starting out and you've  
7 never had managed care, it was a learning process  
8 for everybody -- for management, as well as for the  
9 companies that we were calling on.

10 Q. You said that part of the plan was to  
11 decide what products you were going to sell to  
12 managed care.

13 Was the conclusion you were going to  
14 sell all the ointments and things to managed care?

15 A. We were principally going to promote the  
16 new products and also offer the older products, but  
17 we had never done contracts with these companies.  
18 So it was -- you know, we have to initiate  
19 contracts.

20 We have to understand -- the company  
21 needs to understand, our distribution department  
22 needs to understand -- you know -- how am I going to

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1 ship VA business? Where is VA business going to go?  
2 Where is it going to come from? Who is going to  
3 order it.

4 So there were a lot of things like  
5 that that we had to learn. And we had to pick the  
6 right -- the big customers, the ones that were the  
7 most influential and represented the most dollars to  
8 us -- and then take the new products -- which  
9 represented the more profitable products in the  
10 line, and the ones that you want to let people know  
11 about the quickest before other competition comes.

12 I don't know if that answers your  
13 question.

14 Q. I think it does, in part.

15 Did Taro then go forward and enter  
16 into contracts with various PBMs and HMOs?

17 A. It wasn't PBMs.

18 Here again, it was primarily people  
19 who can purchase product.

20 Q. The contracts with these generic companies  
21 would be largely closed-formulary situations?

22 A. Or GPOs, or other individuals that can

1 basically a purchaser, just like a Walgreens or  
2 anybody else?

3 A. Absolutely.

4 Q. Understood.

5 Sigma-Tau Pharmaceuticals?

6 A. CIGNA?

7 Q. "Sigma-Tau Pharmaceuticals."

8 I'm not a Greek.

9 A. "Sigma-Tau"?

10 Q. "Sigma-Tau."

11 A. I'm sorry.

12 Q. "Sigma-Tau."

13 A. Yes.

14 Q. All right. You worked there from, it  
15 says, 2001, at some point, through March of 2002?

16 A. Basically I was there for a little over a  
17 year.

18 Q. And you were responsible for -- it says,  
19 for prescription products?

20 A. Yes.

21 Q. And the prescription product that  
22 Sigma-Tau --

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1 control or influence compliance.

2 Q. So is that true with all these generic  
3 companies that we're talking about, that the  
4 contracts -- let me finish -- that you would be  
5 entering into would be with individuals that could  
6 enforce compliance -- closed-formulary situations --  
7 you know, the VA, things like that?

8 A. If I understand your question correctly,  
9 that it's people that actually buy product, then the  
10 answer is yes.

11 Q. All right. And not PBMs, but the generic  
12 companies -- the contracting is not with PBMs or  
13 with HMOs that simply reimburse for product, as  
14 opposed to purchase product?

15 A. That -- that's relatively true.

16 And I say "relatively" because there  
17 are so many of them with mail-order businesses.

18 Q. And so to the extent that a PBM or an HMO  
19 has a mail-order business, those are situations  
20 where the generic would be -- the generic companies  
21 with which you've had experience would be  
22 contracting with them directly because they're

1 A. Yes, sir.

2 Q. -- made was a -- had to do with the  
3 end-stage renal dialysis?

4 A. That was the orphan drug indication that  
5 they were approved for.

6 The original indication for the drug  
7 was in infants with failure to thrive, due to inborn  
8 errors of metabolism.

9 Q. It's a nutritional product that you're  
10 selling at Sigma-Tau?

11 A. It's a prescription drug.

12 It's kind of like a protein, a  
13 co-enzyme; and without getting into too much detail,  
14 because I want to make sure you understand it, it is  
15 the chemical that the body itself typically  
16 manufactures that will move fats into different  
17 organelles within the cell so that the cell can  
18 actually create energy, and then gets rid of the  
19 waste products so that they can be excreted.

20 Without it you die.

21 Q. Is it an amino acid?

22 A. Basically.

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1 Q. And it's one of many different products  
2 that are given to a patient that's going through  
3 renal dialysis?  
4 A. Correct.  
5 Q. And you were defending that product  
6 against some generic competition; correct?  
7 A. Not when I started.  
8 I mean, when I actually went to work  
9 for the company I was informed that we would not  
10 have generic competition because we had orphan drug  
11 exclusivity through the year 2006, which ended up  
12 being a major surprise when -- you're right --  
13 generics came a month or two after I got there.  
14 Q. In terms of the end-stage renal dialysis  
15 that Sigma-Tau was selling into, there's -- what? --  
16 three or four big operators that you would enter  
17 into agreements with?  
18 A. That's true.  
19 Q. And did the agreements provide for  
20 exclusivity for the Sigma-Tau amino-acid product?  
21 A. No, they did not.  
22 Q. And what happened when the generic

1 the air with regard to whose they'd pay for.  
2 So they basically will pay for the  
3 generic or the brand.  
4 So any marketing efforts that would  
5 be put into the brand really is the only difference  
6 between the brand and the generic, as far as the FDA  
7 is concerned.  
8 Q. And Medicare reimburses for all of this  
9 treatment after the first year; right?  
10 A. For the most part, yes.  
11 Q. So this is not a situation where you're  
12 contracting with managed-care companies in  
13 connection with entering into some contracts for the  
14 Sigma-Tau product?  
15 A. Contracting with them, no.  
16 Q. And then in your report, Exhibit 1075 --  
17 MR. PARKER: Gordon, are you done  
18 with background now?  
19 MR. DOBIE: No. I want to do his  
20 consulting. And then can we take a break?  
21 MR. PARKER: Okay.  
22 Q. You mentioned that you've consulted with a

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1 products came on?  
2 A. We were pushed for much lower pricing,  
3 which we had to give in order to keep the business.  
4 Q. Was there any advantage of your products  
5 versus the generics, or from the FDA's point of view  
6 were the products simply substitutable?  
7 A. That's an interesting question.  
8 From the FDA's perception, they have  
9 left it more up to CMS. I don't know if CMS was  
10 referred to in Dr. Kolassa's report or not; but it's  
11 the Center for Medicare/Medicaid, something or  
12 other. But it's the old HCFA, Health Care Financing  
13 Administration.  
14 We approached the FDA in order to get  
15 approval for the indications of the product and for  
16 use of the product, so that it would be reimbursable  
17 through Medicare and Medicaid -- well, Medicare  
18 specifically.  
19 And the bottom line is: We ended up  
20 getting -- or they -- this was after I left -- they  
21 ended up getting approval for the indications, but  
22 the actual payment of the product was still up in

1 number of different pharmaceutical companies.  
2 You've got "Odyssey Pharmaceuticals."  
3 Let's talk about that. What have you  
4 done for them?  
5 A. Odyssey was -- and the first couple of  
6 companies that you see on there are related.  
7 Odyssey is the branded division of  
8 Sidmak. Sidmak was looking to bring a couple of  
9 products to market.  
10 My consulting with them was  
11 principally along the lines of looking for and  
12 interviewing companies for a sales force, and with  
13 regard to the marketing of the couple of products  
14 that they were going to bring to the market, first  
15 off.  
16 And this was -- was not strategic in  
17 nature at all. It was mostly looking at and coming  
18 up with appropriate messages for their sales  
19 materials and advertising materials.  
20 Q. Odyssey, that's a biotech company; right?  
21 A. Odyssey is -- no, it's not.  
22 They are a branded division, now, of

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1 Sidmak -- which is a generic company, and they were  
2 just purchased by Plava.  
3 Q. Right. Did Odyssey ever bring any  
4 products to market?  
5 A. Oh, yes. They're in market right now.  
6 Q. What are they bringing to market?  
7 A. I don't even remember.  
8 I do know that they're selling, right  
9 now -- it's a urinary/continence product that they  
10 purchased from Merck. And I cannot remember the  
11 name.  
12 Q. But are there products that you worked  
13 on --  
14 A. That one.  
15 Q. You did work on that?  
16 A. Just -- just for -- just to review the  
17 promotions. That's it.  
18 Q. So you reviewed the promotional material  
19 for the Odyssey urinary/continence product?  
20 A. And there's another product that was  
21 competitive to Sandoz's neoral -- "Cyclosporine  
22 A" -- which they brought to market as well.

1 a -- I mean, it's probably not the  
2 nitty-gritty --  
3 MR. DOBIE: I'm not going to get into  
4 it in any great detail.  
5 But I'm just trying to understand  
6 what you did, because --  
7 A. They wanted to understand the impact of  
8 the United States Pharmacopoeia on their product  
9 line in generics.  
10 Q. They have a generic product line?  
11 A. They have a generic product line, but  
12 that's not what they were looking to find out.  
13 They were looking to find out how the  
14 USP would impact -- or changes to the USP would  
15 impact the introduction by someone else of a generic  
16 of their product.  
17 Q. When did you do that work?  
18 A. Four or five months ago, three months ago.  
19 Q. Who did you report to at Pharmacia on  
20 that?  
21 A. I worked with another consultant, Ed  
22 Thwaite.

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1 And that one, I worked on their -- on  
2 the development of their promotional materials.  
3 Q. Okay.  
4 A. In other words, looking into the market,  
5 seeing what -- you know, patients -- etc.  
6 Q. "Pharmacia," what did you do for them?  
7 A. Pharmacia was a project where they wanted  
8 to understand the impact of USP and changes to the  
9 USP with regard to generics.  
10 By the way, I have confidentiality  
11 agreements with all these companies. Am I --  
12 MR. DOBIE: You can put -- the whole  
13 deposition can be designated "confidential" and  
14 "highly confidential," whatever is appropriate.  
15 THE WITNESS: Does that cover me with  
16 confidentiality.  
17 MR. PARKER: As between our two  
18 companies, it covers.  
19 I'm not sure it helps him with those  
20 third parties.  
21 I wonder if we can, you know, be real  
22 discreet about what you say so we don't have

1 Q. Who at Pharmacia?  
2 A. Don't know.  
3 I shouldn't say that.  
4 I don't remember.  
5 Q. But Pharmacia was looking at how  
6 competition, generic competition, could impact its  
7 branded product?  
8 A. Basically.  
9 Q. You were looking at how it would be  
10 impacted.  
11 Were you asked to figure out how to  
12 defend the branded product?  
13 A. No.  
14 Q. When you were at Sigma-Tau --  
15 A. I was asked to look at what the impact  
16 would be of the USP, or a change in USP, on the  
17 development of a generic product.  
18 That's basically it.  
19 Q. At Sigma-Tau, just to go back to that --  
20 when you say: "Successfully defended our major  
21 brand against 3 generic entrants in our primary  
22 market" -- how did you successfully defend it?

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1 A. By value-added services. By going in and  
2 discussing with them the kinds of things that we can  
3 bring to them, like -- there are mechanisms that you  
4 have to go through in order to decide whether a  
5 patient is a candidate for the product.

6 There are things called "fiscal  
7 intermediaries," which I think you are familiar  
8 with -- you seem to be familiar with -- the Medicare  
9 process.

10 They make their own decisions. So  
11 you have to put together decision trees so that they  
12 understand, when they submit the bill to the fiscal  
13 intermediary, what kinds of things need to be  
14 included on that bill in order to get paid. And  
15 they can change over time.

16 So these are the kinds of value-added  
17 services that we would provide that are not provided  
18 by a generic manufacturer.

19 And the generic manufacturer -- and  
20 it's kind of interesting. The generic manufacturer  
21 does not have in their package insert the indication  
22 for use in dialysis, but that's where all of it's

1 A. The drugs are deemed bioequivalent.

2 Q. What did you do for Sidmak? Is that the  
3 same thing as what we're talking about with Odyssey?

4 A. Pretty much, yes.

5 Q. Anything else?

6 A. When you get to Medirex, Medirex is a  
7 re-packager that was also owned by Sidmak.

8 And it was interesting. I was not  
9 brought into that as a result of Sidmak, so much.

10 They were looking to find ways either  
11 to sell the business, because it was not meeting  
12 their expectations, or to find new customers.

13 So I had to go out and talk to other  
14 generic companies, primarily, as to find out what  
15 the interest would be in this kind of a re-packager;  
16 and the problem that the company had was such that  
17 there was nobody with a great amount of interest.

18 So -- and, frankly, there was nobody  
19 that was interested in buying the company. So they  
20 folded up shop.

21 Q. "PoliChem," that's a veterinary medicine  
22 company in Europe?

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1 being bought and used.

2 So whether they were or were not  
3 allowed to do these kinds of things, I don't know.

4 You know, whether that would be  
5 perceived in some way by the FDA as, you know, "You  
6 guys don't have that indication. Why are you doing  
7 this?" We could do those things.

8 So that's primarily how we kept the  
9 business.

10 Q. Did you point out, to the companies that  
11 were purchasing the Sigma Tau product, the fact that  
12 Sigma Tau's amino-acid supplement product had the  
13 indications and the generics did not?

14 A. Yes. And they didn't seem to care.

15 Q. Was it all three generics that didn't have  
16 the indications?

17 A. No generic can have that orphan drug  
18 indication.

19 Q. Oh, I see. It's the orphan drug  
20 indication, okay.

21 But the FDA has determined that the  
22 products are bioequivalent?

1 A. No, they're not veterinary.

2 "PoliChem" is a manufacturer in  
3 Europe. They were looking to bring some molecules  
4 into the United States, and they were looking for me  
5 to give them an assessment of what the value of  
6 these products were in the United States, as well as  
7 to assess what customers we might approach in  
8 developing alliances.

9 Q. Did any of that involve managed care?

10 A. If you're talking GPOs, yes.

11 Q. Okay.

12 A. If you're talking PBMs, no.

13 Q. Or HMOs that aren't buying the product  
14 directly, it didn't involve that either?

15 A. That aren't buying direct, no.

16 Q. "No," it did not involve?

17 A. It did not include any of those.

18 Q. Understood.

19 "Forrest Labs," what did you do for  
20 them?

21 A. Forrest Labs was looking at a -- at  
22 developing a portfolio of products.

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1 They were looking at, what would be  
2 the impact of several different products; and they  
3 wanted me to forecast those generics for, like, the  
4 next three or four years so that they could  
5 prioritize their activities, their development  
6 activities, on generic products.

7 Q. Did any of that involve managed care?

8 A. No.

9 Q. How about "Astra/Zeneca"; what did you do  
10 for them?

11 A. AstraZeneca -- AstraZeneca actually --  
12 that was an interesting -- AstraZeneca was helping  
13 them to prepare for Prilosec going generic.

14 And I participated.

15 And here again, I have a  
16 confidentiality agreement with them. So I can't get  
17 into too much detail; but I will tell you it  
18 included me preparing an assessment of what their  
19 competition would do, how they would probably do it,  
20 and what would be the impact.

21 And that did include an assessment of  
22 managed care.

1 had to go to a generic -- those kinds of things.

2 Q. Understood.

3 Who did you report to at AstraZeneca  
4 about that?

5 A. My primary contact was Andy Stoutberg, who  
6 is still there.

7 Q. And then the last one you got on  
8 consulting here is "Ruane, Cunniff & Company."

9 A. And they were looking for a -- and that  
10 was just a day project.

11 That was an assessment of the  
12 distribution marketplace; and it was more as a focus  
13 group, if you will.

14 I wasn't in a focus group. It was  
15 more a personal interview.

16 They spent a good day on the phone  
17 with me, to get to understand the distribution  
18 channel and how products moved through the  
19 distribution channel and where the moneys come from  
20 through the distribution channel -- as well as,  
21 where are the actual source of funds, you know, for  
22 a company -- for a wholesaler who works on margins

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1 Q. Well, AstraZeneca -- their product,  
2 Prilosec, is a product that they had on a number of  
3 different exclusives with managed care; right?

4 A. Yes.

5 Q. Okay.

6 A. What do you mean by "exclusives"?

7 Q. They had contracts with various  
8 managed-care organizations that Prilosec would be  
9 the only PPI on their formulary.

10 A. I was not aware of that.

11 Q. Okay.

12 A. That could be, but I was not aware of  
13 that.

14 Q. All right. So that wasn't part of your  
15 analysis?

16 A. No, it was not.

17 Q. All right. So when you say you were  
18 looking at managed care for AstraZeneca on Prilosec,  
19 what were you doing?

20 A. Looking at how the generic companies would  
21 be impacted, how the PBMs would make a decision,  
22 when and where they would make the choice that you

1 of, like, 1 and 2 percent, where do they really make  
2 their money?

3 Q. With AstraZeneca and the PPI, the  
4 contemplated introduction of a generic -- were they  
5 working to figure out how they would defend the  
6 brand in the face of generic competition?

7 A. Yes, sir.

8 Q. Were they also looking at how they were  
9 going to defend the brand, as it relates to their  
10 other competitors in the category -- the Prevacids,  
11 the Protonixes, and the other products in the PPI  
12 category?

13 A. That was beyond the scope of my project.

14 I'm certain they were doing it, only  
15 because of the information that they provided me;  
16 but it's not something that I was involved in.

17 MR. DOBIE: Why don't we take that  
18 break?

19 VIDEOGRAPHER: The time is 10:48.  
20 We are off the record.

21 (A recess was taken.)

22 VIDEOGRAPHER: The time is 10:59.

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1 We're back on the record.

2 BY MR. DOBIE:

3 Q. Mr. Simon, I had some follow-up questions

4 about some of the things we were talking about.

5 You mentioned Warfarin sodium as a

6 product that had been approved by the FDA but not

7 immediately, I guess, reimbursed by various

8 managed-care organizations.

9 Do you recall that testimony,

10 generally?

11 A. Yes.

12 Q. Warfarin sodium, I think you also

13 mentioned, is a narrow therapeutic indication

14 product; right?

15 A. Yes.

16 Q. It was a product that a number of state

17 board of pharmacies concluded that the product could

18 not be substituted until they had reviewed it and

19 approved it as a true substitutable product for the

20 branded; correct?

21 A. Correct.

22 Q. And isn't that one of the reasons why

1 Squibb, with the Estrace product -- were you

2 involved at all with how Estrace was positioned in

3 the marketplace?

4 A. No.

5 Q. Do you know what advantages, if any,

6 Estrace had over Premarin or Cenestin?

7 A. I do not.

8 And Cenestin wasn't a product then,

9 either.

10 Q. Let's look at your report, Exhibit 1075;

11 and I'm interested in page 3 of the report.

12 A. Can I make a comment before we start?

13 There are a couple of things in here

14 that I want to make sure are more clear --

15 specifically, on page 13 where it says "KOLASSA 30."

16 That's Dr. Kolassa's report at page 30.

17 Q. Okay.

18 A. And on Page No. 11, the sentence that

19 starts: "The fact that Cenestin has similar market

20 shares" -- I mean similar to Premarin.

21 I don't know how you read that.

22 Q. You want it to read, the fact that

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1 various managed-care organizations didn't

2 immediately put it on formulary?

3 A. I honestly couldn't tell you.

4 Q. Okay.

5 A. And I couldn't tell you that a lot of them

6 didn't have it on formulary.

7 Are you speaking PBMs at this point?

8 Q. I was following up on your -- were you

9 talking about PBMs when we were talking about

10 before?

11 A. If your question, though, is: Was it on

12 formularies? It very well could have been on PBM

13 formularies.

14 Q. All right. In the situation with Zantac

15 and Glaxo, do you know whether Roche detailed Zantac

16 heavily?

17 A. Yes.

18 Q. Do you know whether they increased the

19 details in order to attempt to increase sales? Was

20 that the goal?

21 A. I would suspect that, yes.

22 Q. And then when you were with Bristol-Myers

1 Cenestin has similar marketshares to Premarin?

2 A. The fact that Cenestin and Premarin have

3 similar marketshares, etc.

4 Q. Anything else?

5 A. That's it.

6 Q. Okay.

7 A. I apologize.

8 Back to your question on page 3.

9 Q. No, no problem at all.

10 Under your heading, it says:

11 "Cenestin is not a 'me-also' product."

12 A. A "'me-almost' product"?

13 Q. Is not a "'me-almost' product"?

14 A. Correct.

15 Q. Let me ask you first:

16 As I understand this, you have got a

17 view that "Cenestin's pharmacokinetic profile and

18 improved dosage uniformity compare favorably to

19 Premarin"; correct?

20 A. Yes.

21 Q. And that's based upon various tests and

22 things that Duramed has done on those products?

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1 A. That's based on the promotional materials  
2 that Cenestin is using, as well as -- yes -- tests  
3 that have been done, like dissolution tests.

4 Q. Let me ask you about one of those  
5 promotional materials.

6 A. And they are really hard to read.

7 Q. Yeah.

8 Here is Exhibit 744.

9 Sir, for the record, Exhibit 744 is  
10 one of the detail aids that Solvay produced in the  
11 litigation.

12 Is this one of the documents that you  
13 reviewed in connection with your service as an  
14 expert for Duramed?

15 A. I am not certain, but it looks familiar.

16 Q. Among other things, it discusses the  
17 various pharmacokinetic and pharmino-dynamic features  
18 of Cenestin; right?

19 A. Where is that?

20 Q. It begins, I think, on page S02531.

21 A. Okay.

22 Q. And there's a "Key Feature."

1 clinical benefits of these pharmacokinetic data, you  
2 should point out that the clinical significance has  
3 not yet been determined.

4 Do you see that?

5 A. Yes, I do.

6 Q. And it says, "However, you may want to  
7 point out that Duramed and Solvay have initiated a  
8 comparative clinical trial."

9 A. Yes.

10 Q. Right.

11 So the "pharmacokinetic benefit" that  
12 is referenced is something that, the clinical  
13 significance of that still hasn't been determined;  
14 right?

15 A. In a clinical study, it has not been  
16 determined.

17 Q. Right. So they take a Cenestin pill, and  
18 they drop it in distilled water, and they see that  
19 the product has improved dissolution profile versus  
20 the Premarin study; correct?

21 A. Yes.

22 Q. What it doesn't do, what hasn't been

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1 It talks about how blood levels for  
2 some estrogens may vary; and Cenestin, under "Key  
3 Benefit," delivers smooth, steady release of  
4 conjugated estrogens -- and so on.

5 A. Yes, sir.

6 Q. And there are a few different pages.

7 Do you understand that this is the  
8 type of detail aid that would actually be given to  
9 the sales force for them to call on physicians?

10 A. Um-hum. Yes.

11 Q. And the benefits that you're describing  
12 are -- some of those benefits, the smooth release of  
13 the estrogen -- smooth, steady release of conjugated  
14 estrogens and blood levels -- improving blood level  
15 for the estrogen from dose to dose -- those are some  
16 of the advantages of the Cenestin product; right?

17 A. Yes.

18 Q. All right. Now, let me draw your  
19 attention to page S02537. And on the right-hand  
20 column, there is a black box.

21 And if you look at the very last  
22 paragraph, it says that if a doctor asks to see the

1 determined, is that the product actually makes  
2 people feel better in a clinical sense; right?

3 That dissolution profile hasn't been  
4 linked to, actually, a clinical difference for  
5 patients; right? That's what that means?

6 A. That's what I think they're saying, yes.

7 Q. All right. And the water -- maybe the  
8 water feels better. There is a smoother  
9 dissolution.

10 But it has never been determined that  
11 it makes any difference in the real world to  
12 patients; right?

13 A. In terms of the dissolution studies you're  
14 referring to, correct.

15 What it speaks about is not something  
16 that has been clinically evaluated.

17 Q. So when we're talking about the benefit or  
18 the fact that Cenestin compares favorably to  
19 Premarin, this is based upon studies for which there  
20 has not been a determination that there is a  
21 clinical significance; correct?

22 A. Correct.

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1 Q. Now, the analogy that you draw in your  
2 report is -- you say that Amoxicillin was launched  
3 at price parity to Ampicillin; and that even though  
4 both products have the same indication, side  
5 effects, and same antibiotic spectrum, Amoxicillin  
6 has a better pharmacokinetic profile and obtained a  
7 higher marketshare with a higher price?

8 A. Correct.

9 Q. All right. And that's the analogy that  
10 you're using with Cenestin; right?

11 That's a good comparison, in your  
12 view?

13 A. That is a comparison where a  
14 pharmacokinetic difference was used to sell a  
15 product.

16 Q. Right. I mean, in fact, Amoxicillin was a  
17 product that was a three-time-a-day product, versus  
18 Ampicillin being a four-time-a-day product?

19 A. Correct.

20 Q. And Amoxicillin was known to absorb better  
21 than Ampicillin?

22 A. Correct.

1 Q. Yes, sir; at the top.

2 A. Yes, sir.

3 Q. Your heading "B."

4 A. Yes, sir.

5 Q. And the point you're making here is that,  
6 even though Cenestin did not have an osteoporosis  
7 indication -- unlike Premarin and the other products  
8 in the estrogen-replacement-therapy category -- that  
9 it's not unusual for a product to come out with one  
10 indication and later get others; right?

11 A. That's correct.

12 Q. All right. And the example that you have  
13 here is Intron A?

14 A. Correct.

15 Q. And Intron A is a product that was made by  
16 Schering?

17 A. Yes.

18 Q. And it is a -- I hope I've got this  
19 right -- an interferon alpha-2B?

20 A. Yes.

21 Q. It's used --

22 A. I'm not sure about the "B"; but, yes, it's

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1 Q. And it was also something that could be  
2 taken on a full or an empty stomach; right?

3 A. Correct.

4 Q. And so, those were all benefits that  
5 helped Amoxicillin sell over Ampicillin and charge a  
6 premium price?

7 A. Correct.

8 Q. And Amoxicillin was launched by Beecham?

9 A. Originally, yes.

10 Q. And they had a large sales force?

11 A. This was back before I even got into the  
12 business.

13 I can't tell you that.

14 Q. Mid-'70s or something?

15 A. Early '70s.

16 I can tell you that I sold Larotid,  
17 which was an Amoxicillin product, to physicians.

18 Q. All right. Then on page 4, we've got:  
19 "Drugs are not always, or even usually, launched  
20 only after obtaining approval for all possible  
21 indications."

22 A. Where are we? Page 4?

1 an interferon alpha.

2 Q. It's an immune system product?

3 A. Exactly.

4 Q. And when it was launched, it was launched  
5 for -- as you note here -- with the only two  
6 indications being rheumatoid and osteoarthritis?

7 A. No; that's Celebrex.

8 Q. I'm sorry.

9 It was launched with "Condyloma" --

10 A. "Condyloma."

11 Q. -- "Condyloma" and "Kaposi sarcoma"?

12 A. Yes.

13 Q. And isn't it true that, even though it was  
14 only launched for those two indications, that the  
15 product wasn't really successful until it got  
16 approval for hepatitis?

17 A. I don't know. I do not know.

18 MR. DOBIE: Let me show you  
19 something.

20 Let's mark this as the next exhibit.

21 Mark this as 1027, I think -- 1077.

22 (Defendant's Exhibit Number 1077 was

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1 marked for identification.)

2 BY MR. DOBIE:

3 Q. I hand you what has been marked as Exhibit

4 1077; and as indicated here, Intron A was

5 originally -- the first indication was hairy cell

6 leukemia in 1986.

7 In '88 it got approval for

8 condylomata. I don't even know how to pronounce

9 that -- c-o-n-d-y-l-o-m-a-t-a.

10 And then in November of '88, it got

11 approval for Kaposi's sarcoma.

12 Do you see that?

13 A. Yes, I do.

14 Q. And then, you see where it was approved

15 for hepatitis in July of 1992?

16 A. Yes, I do.

17 You've got February '91.

18 Q. Yes.

19 A. Hepatitis B in '92.

20 Q. And, sir, you don't know whether or not

21 the sales of this product didn't take off until

22 Hepatitis C was approved; do you?

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1 A. I do not know about the sales of this

2 product.

3 Q. Do you know how the sales of this product,

4 Intron A, compare to the other product that is

5 indicated on Exhibit 1077, which is --

6 A. Roferon?

7 Q. -- Roferon-A?

8 A. I do not -- I have not followed this

9 product, no.

10 Q. All right. Roferon-A is an interferon

11 alpha-2A. It's indicated for hairy cell leukemia,

12 but it does not have the -- it also has the

13 indication for Kaposi's sarcoma. It has indication

14 for Hepatitis B in Canada and in Europe.

15 But do you know what the sales were

16 of Roferon without the Hepatitis C indication?

17 A. No, I do not.

18 Q. Would it surprise you to learn that they

19 were significantly less than the Intron A sales?

20 A. It would not surprise me at all.

21 Q. All right.

22 A. I have not looked at...

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1 Q. You haven't looked at that?

2 A. Correct.

3 Q. All right. Well, in your report you

4 basically are saying that it may not be necessary to

5 have all indications to launch a product.

6 But you'd agree with me that having

7 more indications can significantly impact the sales

8 of a product; correct?

9 A. I don't understand.

10 Having more indications, having every

11 indication that is possible to have, would be very

12 beneficial. I state this in my report. And that, I

13 have no doubt.

14 But it doesn't mean that you don't

15 launch a product because you don't have every

16 indication, as is example with Celebrex.

17 Celebrex is getting additional

18 indications as time goes on, but their original

19 indications for rheumatoid and osteoarthritis are

20 the ones they came to market with.

21 Q. We'll come back to Celebrex in just a

22 minute.

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1 But you'd agree with me that, yes,

2 companies do launch products without all

3 indications, but that the lack of an FDA-approved

4 indication could significantly impact sales?

5 A. No, I won't say that at all.

6 Q. Okay.

7 A. I would say that it depends on what the

8 value is of that indication.

9 If you come out with a product for --

10 if you start adding indications that are nonsense

11 for the product later on, what difference does that

12 make?

13 A great example would be the

14 Sigma-Tau product. When the product was brought to

15 market, it was all orphan drug indications.

16 Q. But the example you picked in your report,

17 sir, was Intron A. All right?

18 A. I picked two examples: Celebrex and

19 Intron A, yes.

20 Q. All right. And with Intron A, you would

21 agree with me that you simply do not know whether or

22 not additional indications that were approved for

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1 Intron A are the reason why the sales ultimately  
2 took off for the product?  
3 A. I am not putting both of those facts  
4 together.  
5 The question is -- or the implication  
6 from the report was that -- it didn't come with all  
7 of its indications, how would it do well?  
8 The point is that a lot of drugs come  
9 to the market without all of the indications.  
10 Q. Okay.  
11 A. I mean -- this is -- what I'm presenting  
12 here doesn't discuss anything about sales value.  
13 Q. Well, that's what I'm asking; and maybe we  
14 can get on the same page.  
15 What you're saying is, is that it's  
16 common to launch a product without all indications;  
17 right?  
18 A. That's what I'm saying.  
19 Q. You're not saying that having all  
20 indications doesn't have economic value?  
21 A. I'm not saying that.  
22 Q. Understood.

1 A. I don't know that.  
2 I know that, to date, those would be  
3 the two most important indications.  
4 Q. Do you also know that Celebrex was  
5 launched with a huge sales force?  
6 It was Searle along with Pfizer  
7 working together?  
8 A. Yes.  
9 Q. Something like --  
10 VIDEOGRAPHER: I need to change  
11 tapes.  
12 MR. DOBIE: Okay. Let me just -- do  
13 I have one question, or no?  
14 VIDEOGRAPHER: Go ahead.  
15 Q. -- something like 4,000 reps to launch  
16 Celebrex?  
17 A. Was it Searle and Pfizer?  
18 Q. (Counsel nods head.)  
19 A. Okay. It could be.  
20 Q. And do you know whether they launched --  
21 over 3,000 of these sales reps launched Celebrex in  
22 either -- when they were promoting it, it was

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1 And as it relates to Cenestin and the  
2 osteoporosis indication, not having an osteoporosis  
3 indication -- I mean, having -- let me restate it.  
4 As it relates to Cenestin, having an  
5 osteoporosis indication could have economic value;  
6 correct?  
7 A. I would say yes; correct.  
8 Q. All right. Now, let's talk about  
9 Celebrex.  
10 Celebrex is a Cox-2 inhibitor;  
11 correct?  
12 A. Correct.  
13 Q. It competes with Vioxx?  
14 A. It competes with NSAIDs and Vioxx.  
15 Q. And it's a product that was made by  
16 Pharmacia, a company that you had some familiarity  
17 with -- and now owned, I guess, by Searle -- or  
18 Searle, now owned by Pharmacia?  
19 A. Correct.  
20 Q. And Celebrex was launched with its two  
21 most important indications first; was it not?  
22 Rheumatoid and osteoarthritis?

1 detailed in either the first or second detail  
2 position?  
3 A. I don't know that, but that would not  
4 surprise me.  
5 Q. And would you agree with me that having  
6 that big sales force like that and having launched  
7 Celebrex with the two most important indications  
8 first, that that could be one of the reasons why  
9 that product was very successful coming right out of  
10 the box?  
11 A. I would say that that's probably very  
12 important, yes.  
13 MR. DOBIE: All right. Let's change  
14 the tapes. Thanks.  
15 VIDEOGRAPHER: The time is 11:22.  
16 This is the end of Tape No. 1.  
17 We're going off the record and on to  
18 Tape No. 2.  
19 (A recess was taken.)  
20 VIDEOGRAPHER: The time is 11:23.  
21 This is the beginning of Tape No. 2.  
22 We're back on the record.

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1 BY MR. DOBIE:

2 Q. On page 4, the heading: "Cenestin was

3 offered in the necessary strengths" -- again, this

4 is a place where you discuss how Cenestin was

5 launched with a .625 milligram and .9 dose.

6 But the 1.25 dose was released within

7 eight months of the product launch; right?

8 A. Yes.

9 Q. Now, let me ask you about that.

10 The time of launch, Cenestin only had

11 this .625 and the .9 -- which were about 73 percent

12 of prescriptions written; correct?

13 A. Okay. I think that's about right.

14 Q. Here's what I'm wondering: Later on in

15 your report you talk about spillover.

16 A. Correct.

17 Q. Do you think there could be a spillover --

18 if a doctor learned that Cenestin was not offered in

19 a 1.25 milligram strength, that he might be hesitant

20 to prescribe Cenestin at the lower dosage?

21 A. I honestly couldn't answer that question.

22 My experience is that a physician

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1 that gets a product that is working, if he wants to

2 adjust the dose, always has the option of giving two

3 tablets to the patient and upping the dose.

4 But it certainly would be easier to

5 take one pill instead of two.

6 Q. Right.

7 A. I --

8 Q. Easier and less expensive; right?

9 I mean, taking two tablets is going

10 to cost you twice the price -- assuming that the

11 1.25 is less expensive.

12 And they usually are; right?

13 A. I -- what do you mean, "less expensive"?

14 Q. Well, did you look at the prices, for

15 example, for Cenestin and Premarin, and whether,

16 economically, it makes sense for somebody to take

17 two Cenestin tablets?

18 A. Twice as expensive to who?

19 Q. For the patient or for the managed-care

20 organization, whoever is paying for the product.

21 A. I -- the patient is not going to see any

22 difference in price on managed care. The patient is

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1 going to pay the same price.

2 Q. How about managed care?

3 A. Managed care doesn't pay for the product.

4 The patient pays for the product.

5 Q. Are you aware of any physicians that

6 are -- or managed-care organizations -- that told

7 Duramed that they were -- that it was okay with them

8 to go ahead and buy two tablets if they needed to

9 titrate up, as opposed to --

10 A. No. Am I aware of that? Absolutely not.

11 Q. Okay.

12 A. And is it the best of all possible

13 scenarios to be in? I wouldn't say that either.

14 Q. Okay.

15 A. What I would say is that the products --

16 by the time they really got out and were selling

17 these products, they had the 1.25-milligram tablet

18 within eight months.

19 So they had all the strengths when

20 they were promoting these doctors, within eight

21 months -- and certainly for the majority of the year

22 2000.

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1 Q. All right. Have you looked at the

2 documents about various managed-care organizations

3 that were approached in '99 and said that they would

4 not consider Cenestin until they obtained approval

5 for the 1.25?

6 A. I am -- is there any one in particular

7 you're referring to?

8 Q. Well, there's -- I think there's a number

9 of them that are out there.

10 But are there any that you're

11 familiar with, having reviewed the documents?

12 A. I was familiar with the documents; and I

13 saw that PCS put it on at least their open

14 formularies, even without it.

15 Q. And what are you referring to when you say

16 PCS put them on their open formularies?

17 A. The open formularies that PCS offers or

18 has, they offered the product.

19 Now, I don't know if that was in '99

20 or before the 1.25. I think it was before the 1.25

21 as well.

22 Q. So your understanding is that the 1.25

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1 wasn't an issue for PCS.

2 Are there any others that you can

3 refer to?

4 A. I cannot.

5 I can tell you, I do remember reading

6 where some of the managed-care organizations did

7 mention the lack of a 1.25 milligram. Yes.

8 Q. Let's look at page 5 of your report and

9 heading "D." This is the discussion of the "Class

10 Effect."

11 A. Um-hum.

12 Q. And you talk about how class effects are

13 an integral part of a pharmacist's education, and so

14 on.

15 Do you teach pharmacists?

16 A. No.

17 Q. Have you ever taught pharmacists?

18 A. Yes.

19 Q. When?

20 A. As a -- when I was in my last year of

21 pharmacy school, I taught the manufacturing lab at

22 Ohio Northern University.

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1 Q. When was the last time --

2 A. That was in 1974, a long time ago.

3 Q. When was the last time you looked at a

4 curriculum for a pharmacist's education?

5 A. It has been a long time.

6 Q. Do you consider yourself an educator?

7 A. No, I do not.

8 Q. Have you written, at all, any

9 publications?

10 A. No, I have not.

11 Q. How about books, anything like that?

12 A. No, sir.

13 Q. Did you do a thesis in college?

14 A. No, sir.

15 Q. Are you familiar with the

16 pharmaceutical-industry educational literature?

17 A. What do you mean?

18 Q. Could you name, for example, for me, the

19 leading pharmaceutical educational journals?

20 A. "Journals"?

21 Q. Journals, magazines, sources.

22 A. If you're speaking peer-reviewed things,

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1 like disease and therapeutics -- I do not typically

2 read those. So I --

3 Q. How about things that are specifically

4 related to pharmacists?

5 A. Like?

6 Q. American Journal of Pharmaceutical

7 Education.

8 A. Pharmaceutical education journals? No, I

9 would not read that.

10 Q. Okay.

11 A. Trade journals about what's going on in

12 the industry -- drug topics, U.S. pharmacists, those

13 kinds of things -- yes.

14 Q. All right. So when you say in your report

15 this is how it's taught, what you're talking about

16 is: How this is how it was taught to you back at

17 Northern Ohio in 1974?

18 A. That's correct.

19 Q. All right. And the way it was taught --

20 was it not? -- was that you would start out with an

21 overview of the class of pharmaceutical products.

22 So if, for example, on a particular

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1 day, if you were talking about -- you list here

2 Benzodiazepines -- you would start out with a --

3 A. Pretty good.

4 Q. -- with a discussion of that class of

5 products, that category of products,

6 Benzodiazepines.

7 And then -- right? That's how it

8 would go?

9 But then, isn't the next part -- I

10 mean, that might be -- what? -- ten minutes, fifteen

11 minutes. And then it would describe, generally,

12 those are the sedatives. And then you would learn

13 all of the differences between the products within a

14 class.

15 Isn't that how it's typically taught?

16 A. Typically -- well, certainly not fifteen

17 minutes.

18 The way that I was taught was to look

19 at a class of drugs -- let's say, Benzodiazepines.

20 And you would spend a day talking about it in your

21 pharmacology.

22 You'd also talk about how it

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1 interacts physically in your physiology class.  
2 So you might be covering that same  
3 class of products in two or even three different  
4 classes.  
5 And when it got to antibiotics, it  
6 was even -- even -- you know, you'd bring in  
7 microbiology, etc.  
8 But, yes, you would learn -- you  
9 would start with learning the class of drugs. Then  
10 you would key in on the pharmacokinetics of the  
11 drugs and what made the drugs different.  
12 For example, if -- to use  
13 Benzodiazepines -- if I'm looking at a product like  
14 Valium, I would learn about Valium and all of its  
15 six or seven different active metabolites.  
16 And I would learn about  
17 structure-activity relationships, which is what  
18 you're talking about in medicinal chemistry -- which  
19 is another class.  
20 That would then talk about how are  
21 these drugs and what are the differences in the  
22 drugs -- what do those differences mean,

1 different Benzodiazepines that are used for  
2 different purposes?  
3 A. Correct.  
4 Q. I mean, they're all sedatives. But some  
5 of them, like a Librium, is not nearly as strong as  
6 something like a Versed; right?  
7 A. Well, first, a Versed is an injectable.  
8 Versed is a water-soluble Benzodiazepine.  
9 It does the same thing as Valium.  
10 The only difference is that they use it as an  
11 injectable because it's -- does not have the same  
12 sting as Valium injectable does.  
13 It's a much preferred drug.  
14 Also, it causes a little bit  
15 different amnesiac effect.  
16 Q. Right. It's usually the amnesias; right?  
17 A. But every single thing that Versed does,  
18 Valium does.  
19 Q. Isn't there a lot of difference within  
20 Benzodiazepines, just in terms of the strength and  
21 the power of the products?  
22 A. There's differences with respect to -- the

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1 pharmacokinetically?  
2 Is that what you're asking?  
3 Q. Yes. I think we're on the same page.  
4 In other words, you learn about the  
5 class of the products, generally, and how the  
6 molecules tic, as it were.  
7 But then you do -- you're not denying  
8 that there's differences within Benzodiazepines, for  
9 example -- I mean, significant, huge differences?  
10 And doctors and managed-care organizations look at  
11 those products differently within that class?  
12 A. I would say that you're correct.  
13 Q. So, for example, you've got Valium here;  
14 and you've got Librium and your list of  
15 Benzodiazepines in your report.  
16 Those are both products made by  
17 Roche; right?  
18 A. Um-hum. Yes.  
19 Q. And they also make other products, like  
20 Dalmane and Versed; right?  
21 A. Correct.  
22 Q. And so they've got a whole group of

1 answer, in a glib way, is for me to easily say yes.  
2 But there's more to it than that.  
3 Q. I guess that's what I'm saying: There's  
4 more to it.  
5 In other words, you're talking about  
6 class effect -- okay? -- in this section of your  
7 report.  
8 And I understand that they're all  
9 sedatives. But on the other hand, there are big  
10 differences in products.  
11 Halcion is a Benzodiazepine. That's  
12 called "the hammer"; right? That's the nickname for  
13 that product?  
14 A. I don't know that, but you could be right.  
15 Q. And some of the products, there are  
16 nicknames for these products in the market.  
17 "Rufies," that's a product that you  
18 see that -- there's a whole criminal drug problem  
19 with rufies.  
20 A. But the point is, if I understand your  
21 question: The drugs themselves still are going to  
22 impact that same receptor site. They're still going

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1 to do pretty much the same thing.

2 There is a difference with which --

3 at which time it's absorbed. There are

4 pharmacokinetic differences.

5 You know, one might be absorbed

6 faster than the other. One might get out of the

7 body -- for example, you mentioned Dalmane and

8 Halcion.

9 Q. Right.

10 A. Halcion has a very short duration of

11 action. It's eliminated. There's --

12 pharmacokinetically, it's eliminated quicker. So

13 it's out of the body quicker than Dalmane.

14 But they're both used for the same

15 purpose.

16 Q. Right. Well, they can be treated for

17 anxiety.

18 Some of these products are actually

19 indicated for epilepsy, though; right?

20 A. That's true.

21 Q. Some of these products are considered

22 minor tranquilizers, and some of them are considered

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1 hypnotics; right?

2 A. That's -- yes.

3 Q. And a doctor and a pharmacist -- when

4 they're learning about these different products,

5 they learn about the differences in those products.

6 And those differences can have a

7 real-world impact in how they're prescribed; right?

8 A. They learn that they all have a particular

9 similar action: This one may be stronger in this

10 way. This one may be stronger in this way.

11 You're absolutely right.

12 You could use -- as a matter of fact,

13 Benedryl -- case in point: They used the side

14 effect of Benedryl as an over-the-counter sleep aid.

15 But the point is that the drugs

16 themselves do the same things. One may have a

17 stronger action this way than the other, because

18 it's a different type -- a different molecule. It's

19 turned different. It does something different.

20 But they're still interacting at the

21 same receptor site.

22 Q. I'm not disagreeing with you on that.

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1 I guess what I'm saying is: The

2 differences in these products, within the class,

3 impact physicians' prescribing behavior; right?

4 A. Yes.

5 Q. And those differences will also impact the

6 sales of the product; right?

7 A. Yes. And the way they're sold to the

8 physicians and -- exactly.

9 Q. Sure.

10 The other thing I wanted to ask you

11 about in the same section on the class effect is:

12 You have a discussion about how

13 Wyeth's birth-control products are prescribed by

14 physicians to treat acne, even though they don't

15 have the indication on their package insert.

16 A. Correct.

17 Q. Isn't it true that the acne benefit for

18 birth-control products is something that has been in

19 the medical literature since the 1970s?

20 A. I don't know that, but it's possible.

21 Q. And is it also possible that doctors could

22 be prescribing Wyeth birth-control products for

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1 having the incidental benefit of treating the acne

2 based upon scientific studies like that and having

3 20 or so years of experience in doing so?

4 A. That's an interesting premise. Let me see

5 if I understand the question.

6 What you're saying is that, because

7 it has been in the literature the doctors could

8 assume that other products that aren't necessarily

9 indicated for treatment of acne could also be used.

10 Q. No. What I'm saying is this:

11 You're saying in your report that

12 doctors just assume class effect; and so doctors

13 would assume that Cenestin would have the

14 osteoporosis indication.

15 And what I'm suggesting the

16 difference between the acne situation and Cenestin,

17 is that doctors have been prescribing -- they may

18 see the same woman for, you know, 10 or 15 years;

19 have prescribed her the birth-control pills; learned

20 that, in fact, in the real world that the product

21 did provide her with an acne benefit.

22 That's not the same thing -- you

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1 would agree with me, would you not? -- as a doctor  
2 looking at Cenestin, a brand-new product on  
3 market -- they don't have experience -- they would  
4 not have experience that the product -- that  
5 Cenestin did, in fact, provide an osteoporosis  
6 benefit?  
7 A. I don't know that that's true.  
8 I certainly will agree with you that,  
9 in terms of them having experience with  
10 conception-control products, that they have seen the  
11 benefit and because of that -- their empirical, if  
12 you will, experience -- that they've decided that  
13 they can do this.  
14 I can tell you that I was told by a  
15 sales rep that, you know, doctors are indeed making  
16 that assumption. They're basically telling them,  
17 "Hey, they all do it."  
18 Q. They all provide that acne benefit?  
19 A. They all provide that acne kind of  
20 prevention.  
21 Q. Okay.  
22 A. So if that answers your question...

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1 Q. I think we're on the same page on that.  
2 I guess -- let me just ask it --  
3 A. But you asked two questions.  
4 Q. Yeah. So let me follow up on that with  
5 Cenestin. Okay?  
6 Are you aware, in anything that  
7 you've read as an expert witness in this case or  
8 outside, where doctors have assumed that Cenestin  
9 has the class effect for osteoporosis?  
10 A. Absolutely.  
11 Q. What is that?  
12 A. The market research.  
13 The market research that was done by  
14 Wyeth showed that doctors and even pharmacists  
15 perceive this effect, because it's got the same --  
16 even though it's not considered a "bioequivalent"  
17 product, it does have the same molecules in it.  
18 Q. Let me make sure I understand what you're  
19 saying.  
20 The "market research" that you're  
21 referring to, that's market research that was done  
22 by Wyeth?

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1 A. Yes, sir.  
2 Q. And do you know whether in that market  
3 research -- whether there was an assumption that the  
4 product was, in fact, approved with an osteoporosis  
5 indication?  
6 A. I don't know that indications were  
7 mentioned in the market research at all.  
8 Q. Do you know whether or not in the market  
9 research the physicians or pharmacists are simply  
10 told that this is another conjugated estrogen; and  
11 they are not told, one way or another, about whether  
12 the FDA has come out and affirmatively stated, "This  
13 product is not approved for long-term use. This  
14 product is not approved for osteo"?  
15 A. I do not know whether that kind of  
16 disclaimer was put into the research.  
17 Q. You're aware, are you not, that the FDA  
18 has affirmatively stated that Cenestin cannot be  
19 promoted for long-term use, like osteoporosis?  
20 A. Repeat the question.  
21 Q. You're familiar that the FDA has come out  
22 with a directive that Cenestin cannot be promoted

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1 for long-term use for treatment of things like  
2 osteoporosis?  
3 A. I believe that I have read something about  
4 that.  
5 Q. Okay.  
6 A. Yes.  
7 Q. And so it's not just simply a situation  
8 where Cenestin doesn't have the indication.  
9 The FDA actually has a document that  
10 affirmatively states that the product cannot be  
11 promoted and is not approved for long-term use for  
12 osteoporosis; right?  
13 A. I believe that -- yes.  
14 Q. All right.  
15 A. I believe you're correct.  
16 Q. And would you agree with me that having  
17 something like that out in the marketplace is more  
18 likely to prevent managed-care organizations from  
19 assuming a class effect, than a situation where it's  
20 simply silent -- in terms of whether or not there is  
21 a class effect for a product?  
22 A. I guess I don't understand the question

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1 completely.

2 If -- you're asking me if they would

3 turn the product down -- managed care, that is,

4 would turn the product down for formulary inclusion

5 because of lack of an osteoporosis indication?

6 Q. No. Let me ask it -- I'm trying to just

7 address the particular point here, the class effect;

8 okay?

9 Your example with Wyeth's

10 contraceptives -- okay -- there wasn't an FDA

11 document that came out and said, "This product is

12 not approved" -- "affirmatively not approved for

13 prevention of acne. This product cannot be promoted

14 for the use of acne." It's simply silent; right?

15 Whereas, with Cenestin, the FDA has

16 out and out -- gone out and affirmatively stated

17 that the product is not approved for osteoporosis

18 and not approved for long-term use.

19 And I'm wondering whether, in your

20 view, that difference could impact whether or not

21 managed care would assume a class effect.

22 A. I will tell you that I doubt that there

1 sales group at Viking.

2 Q. Do you know whether or not the Blue Cross

3 and Blue Shield of California -- or, I'm sorry, Blue

4 Shield of California -- again, this is an example --

5 on its own reviewed the medical literature, reviewed

6 the FDA information, and concluded that they could

7 not simply conclude that there was a class effect,

8 in light of the FDA's affirmative statement that the

9 product is not approved for long-term use for

10 osteoporosis?

11 A. I've not seen anything specifically

12 mentioning class effect -- either that, or it was

13 something that I just totally glanced over when

14 reviewing.

15 MR. DOBIE: Let me ask you about the

16 documents that you did review, because I was

17 curious about that.

18 Could you mark that as the next

19 exhibit.

20 (Defendant's Exhibit Number 1078 was

21 marked for identification.)

22 BY MR. DOBIE:

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1 would be any difference; and I'll tell you why:

2 Because I don't see those letters affirmatively

3 going from the FDA directly to physicians or other

4 people in the industry.

5 I see them potentially being brought

6 by Wyeth-Ayerst, which easily could have been done

7 by Johnson & Johnson for anyone else that went out

8 to promote their product for an acne indication.

9 So if you're asking me: What's the

10 impact of that specific event, of the FDA saying --

11 you know, even if it's in a press release, I doubt

12 that there's a lot of physicians that look at the

13 press releases and things like that.

14 So, I don't know how I would --

15 Q. Fair enough.

16 Well, do you know, for example,

17 whether or not Aetna looked at the FDA's

18 determination that the product wasn't approved for

19 long-term use in not putting it on formulary?

20 A. I don't know that for a fact.

21 I do know that there were some

22 companies that mentioned that to the managed-care

1 Q. Exhibit 1078.

2 Mr. Simon, we've given you Exhibit

3 1078. This contains a list of the documents, it

4 says were provided to Paul Simon.

5 A. Um-hum.

6 Q. Do you know how these documents were

7 selected to provide to you?

8 A. I asked for marketing materials -- which

9 was specifically what my directions were, to be the

10 marketing expert -- and to have those sent to me,

11 which I believe was done.

12 Also, contracts were sent to me.

13 Q. Did you ask to review any depositions of

14 employees from Duramed?

15 A. I did get some field communications.

16 I did get -- I did -- I'm trying to

17 think if I requested specific -- the only thing I

18 requested specifically was everything that would be

19 included in Dr. Kolassa's arguments or on his

20 deposition or report.

21 Q. But this is the list of documents that you

22 reviewed; right?

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1 A. Well, there's a lot of documents there. I  
2 can only assume that this is the list.  
3 Q. Well, it doesn't appear that you reviewed  
4 any depositions of anybody from Duramed; is that  
5 correct?  
6 A. From Duramed?  
7 Q. Yes, sir.  
8 A. No.  
9 Q. And it doesn't appear that you reviewed  
10 any depositions of anybody from Wyeth; right?  
11 A. Wyeth, individually? No.  
12 Dr. Kolassa? Yes.  
13 Q. So the only deposition that you've read in  
14 this case that you're basing your opinion on is the  
15 deposition of Dr. Kolassa and Mike Williamson, who  
16 worked for Solvay; correct?  
17 A. I did get Mike Williamson's, by the way.  
18 Q. That's what I said.  
19 A. Yeah.  
20 Q. So those are the only two depositions that  
21 you're basing your opinion on?  
22 A. Complete depositions, yes.

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1 There were little snippets of things,  
2 obviously, that were included in some of  
3 Dr. Kolassa's things.  
4 I did get communications -- you know,  
5 field communications, which I had requested. There  
6 are field communications in here.  
7 But in terms of depositions, no.  
8 Q. Sir, are you familiar with the medical  
9 literature that speaks to evidence-based medicine?  
10 A. Only as a result of having read  
11 Dr. Kolassa's report.  
12 Q. You didn't read Dr. Schondelmeyer's  
13 deposition or report?  
14 A. No.  
15 Q. Do you disagree with Dr. Schondelmeyer,  
16 that evidence-based medicine should be the method  
17 that's utilized by doctors and managed-care  
18 organizations in determining what products should be  
19 prescribed?  
20 A. Without knowing that much about  
21 evidence-based medicine, I'd have a difficult time  
22 answering that question. So...

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1 Q. You're not disagreeing with the notion  
2 that doctors and managed-care organizations that are  
3 involved in trying to make a decision of what  
4 product they should either provide on a formulary or  
5 prescribe to the patient directly should make use of  
6 the medical literature and the evidence that's out  
7 there in the literature supporting a particular  
8 product; right?  
9 A. Am I saying that they shouldn't look at  
10 that? Absolutely not. I think they should look at  
11 that.  
12 Q. All right. And would you agree with me  
13 that in 1999, when Cenestin was launched, and in  
14 2000, when as you put it before they really got up  
15 and running -- that the evidence supporting  
16 Premarin -- the medical literature that was out  
17 there, the studies -- that that was -- and even  
18 patients' and doctors' experience with the  
19 product -- that was a distinct advantage that  
20 Premarin had over Cenestin?  
21 A. Would I say that it would be valuable to  
22 have 3,000 studies, as they were promoting it?

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1 Q. Yes.  
2 A. You're asking me an interesting question,  
3 especially in light of what's going on today.  
4 I think it would be absolutely great  
5 for every product to come out to have that; but as  
6 you know in the case of products that are launched,  
7 I don't know of anybody that comes out with 3,000  
8 studies.  
9 So I don't know how to assess what's  
10 the value of having that wealth of data. I don't  
11 know.  
12 Would it be valuable? Sure.  
13 Would it be something that would  
14 maybe say I'd get 45 percent marketshare instead of  
15 50 percent marketshare? I don't know. I honestly  
16 don't know.  
17 Q. Price -- this is page 6 of your report.  
18 A. Um-hum.  
19 Q. The heading says: "Price was not the  
20 issue."  
21 Let me ask you first: Are you aware  
22 of any witness from a managed-care organization or

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1 within Duramed, within Cardinal, within Solvay, that  
2 has testified that they believe that the price of  
3 this product was appropriate?

4 A. I am aware that the -- that an individual  
5 from NPA made a comment to that effect.

6 Q. That the price was not appropriate?

7 A. That the price was too high.

8 Q. Are you aware of others that thought the  
9 price was too high?

10 A. I can't speak to who, no.

11 Q. Were you aware, for example, when you  
12 wrote this report that the head of managed care for  
13 Duramed believed that the price of the product was  
14 too high?

15 A. I was aware that there were people out  
16 there that looked like -- or that expressed a  
17 concern that the price might be too high.

18 Q. Were you aware that the person,  
19 Mr. Neeley, who was responsible for calling on  
20 managed care -- Mr. Neeley was with Viking, and  
21 Viking was the organization responsible for calling  
22 on managed-care companies -- that he too believed

1 Q. So that's calling on managed care at Teva,  
2 which was a generic company?

3 A. Um-hum.

4 Q. And Prilosec, where you were asked to do a  
5 study of the impact that generics would have on  
6 Prilosec's marketshare once the generics came on  
7 line?

8 A. (Witness nods head.)

9 Q. What is it about the Prilosec experience  
10 that leads you to believe that the price was  
11 irrelevant?

12 A. First off, it's not just -- you know, I  
13 can't just say that nothing else that I did over my  
14 history is relevant.

15 I've been in the business for a long  
16 time, and it isn't just being drawn from these  
17 projects. The Prilosec project is the most recent  
18 one.

19 But quite frankly, I have been  
20 talking to these people. I know several of these  
21 individuals for a long time, including the time that  
22 I was at Teva, and actually did call on them.

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1 that the price was too high?

2 A. I don't know if it was Mr. Neeley's report  
3 that I read or not, but I did read a report from an  
4 individual expressing a desire for them not to do a  
5 price increase.

6 And all I can say is: That's real  
7 typical for a sales individual to make that kind of  
8 comment, because they have to go out and sell  
9 products.

10 The issue, I guess, that I'm having a  
11 problem with is that when it comes to putting a  
12 product onto a managed-care formulary, the price  
13 that's presented to the marketplace as an AWP is of  
14 absolutely no relevance -- or maybe I shouldn't say  
15 "of no relevance," but it is of little relevance, in  
16 my experience.

17 Q. What is the experience that you have that  
18 you're drawing on to reach that conclusion?

19 A. Having done one thing: The project for  
20 Prilosec.

21 And the other is calling on  
22 managed-care customers while I was at Teva.

1 And the issue of price -- they're  
2 public companies. They need to make money. They're  
3 looking at: What are the rebates going to generate  
4 for me?

5 And I think any of the companies that  
6 you talk to, any of the PBMs or people that are  
7 involved in these formulary decisions, are going to  
8 tell you that the cost is the last thing that they  
9 look at.

10 Q. So the product attribute is the first  
11 thing?

12 A. The product itself -- I mean, they will  
13 look at that. You know, what is it?

14 Now, the reality of it is that, yes,  
15 indeed, they will look at what the rebates look like  
16 and eventually what it is going to end up in the  
17 marketplace.

18 Q. So eventually they look at rebates and  
19 price; right?

20 A. I think -- yes.

21 Q. And are you aware that there are numerous  
22 managed-care organizations that repeatedly informed

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1 Duramed that deep discounts on Cenestin were  
2 necessary because there was no demand for the  
3 product?  
4 A. No, I'm not aware of that.  
5 I don't know what one has to do with  
6 the other.  
7 Q. Are you aware of --  
8 A. Are you saying that they required deep  
9 discounts because there was no demand? I did not  
10 see that.  
11 Q. Well, one strategy -- right? -- to launch  
12 a product -- and we're talking about Celexa, I  
13 think -- have we talked about Celexa?  
14 A. No; but you can talk about them.  
15 Q. Okay. Celexa is a product that competed  
16 with Prozac?  
17 A. Um-hum.  
18 Q. And it was manufactured by whom; do you  
19 know?  
20 A. Prozac? Eli Lilly.  
21 Q. No; Celexa.  
22 A. Forrest.

1 Q. Have you seen literature to the effect  
2 that doctors prescribe different products for  
3 cash-paying customers versus insured customers?  
4 A. Tell me what you mean by "different  
5 products."  
6 Q. Different pharmaceutical products within a  
7 particular class, depending upon whether they're  
8 insured or if they're cash-paying customers.  
9 A. I am sure -- and if you look at some of  
10 the research, you'll see this as well -- some of the  
11 doctors in the Wyeth research made comments to the  
12 effect that that's why I write "medically  
13 necessary," etc. -- so that they aren't substituted  
14 at the drugstore.  
15 But I am absolutely certain that  
16 there are doctors that will do different prescribing  
17 habits and provide generics or something like that  
18 to someone who is an elderly cash-pay patient.  
19 If that's where you're going, I do  
20 know that there are examples of that, yes.  
21 Q. You have seen the data that suggests --  
22 A. I have not seen the data. I'm speaking,

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1 Q. Forrest.  
2 And did you have any involvement in  
3 Celexa --  
4 A. No.  
5 Q. -- when you were consulting with Forrest?  
6 Do you know that the strategy for  
7 Celexa was to launch at a big discount to Prozac?  
8 A. I'm aware that there have been products  
9 brought to market that way, yes.  
10 Q. And are you aware that physicians would  
11 prescribe Celexa for the cash -- their cash  
12 patients?  
13 A. No, I'm not aware of that.  
14 Q. Are you aware of any of the literature  
15 that suggests that doctors prescribe different  
16 products for patients that are, let's say, in the  
17 Medicaid class versus the insured class?  
18 A. That is totally contrary to what I  
19 understand.  
20 Q. So you haven't seen literature to that  
21 regard?  
22 A. No, I have not.

1 experience.  
2 Q. I see.  
3 Well, are you aware of -- in this  
4 case -- of managed-care organizations suggesting  
5 that what Duramed should have done was price the  
6 product at a deep discount, build up demand within  
7 the cash-paying part of the market and  
8 Medicaid/Medicare, and then once you have demand  
9 that they would consider the product on formulary?  
10 A. You're losing me again.  
11 Are you saying that Wyeth would  
12 propose that?  
13 Q. No; that managed care organizations  
14 suggested that to Duramed.  
15 A. I'm not aware that managed care had  
16 suggested that, no.  
17 And -- well...  
18 Q. Would you agree that an increase in  
19 rebates would result in a lower net price paid by  
20 managed-care organizations for Premarin?  
21 MR. PARKER: I just didn't hear the  
22 question. Could you read it back?

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1 MR. DOBIE: Yeah.

2 Q. Would you agree that larger rebates would,

3 in turn, result in a lower net price for Premarin

4 for managed-care organizations that were reimbursing

5 for the product?

6 A. It's a difficult question to answer, and

7 I'll tell you why. I'll elaborate.

8 Managed-care companies are in the

9 business of doing several things -- one of which is

10 to get rebates and to share those rebates,

11 sometimes, with their customers, the employers.

12 So will it actually reduce the price

13 or the cost or the net cost, if you will, to managed

14 care? I think it would be infinitesimally

15 different.

16 The answer to your question is:

17 Obviously, if you buy something or you're going to

18 get someone to give you \$10 every time somebody does

19 something for you, and the money that's paid is to

20 put the product on the formulary -- then, yes, I

21 would have to say perhaps you're correct.

22 But it's really tough -- it's tough

1 A. Right.

2 Q. And you want to say, "I don't know for

3 certain why Duramed or Viking contained these

4 figures"; right?

5 A. Um-hum.

6 Q. But then you go on, and you look at the

7 Novartis report and you look at some other documents

8 from Solvay and Wyeth; right?

9 A. Well, and I also looked at other documents

10 from Viking, which also represent the same --

11 basically the same numbers -- that, no, in fact,

12 they didn't have access to 60 to 70 percent.

13 It's like the people from Viking were

14 saying, "Yes, we do"; and then they were saying,

15 "Oh, no, we don't. Here is what it is."

16 Q. Let's look at some of those documents and

17 see whether or not we can get any clarification

18 here.

19 First, let me show you what has been

20 marked as Exhibit 301.

21 These are already marked. So we're

22 all set there.

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1 for me to assess it. It's a complex question.

2 MR. DOBIE: Okay.

3 Let's take a two-minute break, if we

4 could.

5 VIDEOGRAPHER: The time is 12:08.

6 We're off the record.

7 (A recess was taken.)

8 VIDEOGRAPHER: The time is 12:16.

9 We're back on the record.

10 BY MR. DOBIE:

11 Q. Sir, can I refer you to page 7 of your

12 report, the Roman numeral IV: "Cenestin did not

13 have equal access to 60-70% of managed care lives."

14 A. Correct.

15 Q. Now, you say here that you don't -- you've

16 reviewed and seen documents that indicate that

17 Cenestin had access to 60 to 70 percent of the

18 managed-care lives; right?

19 A. Yes. I've seen documents where people

20 have claimed that they had that.

21 Q. And the people that have claimed that --

22 it's not Wyeth, it's Duramed; right?

1 For the record, Exhibit 301 is a copy

2 of a memo from Mr. Carter, who is the head of

3 managed care at Duramed, to Barb Casey, at Solvay --

4 referencing, I guess, a planned meeting with Jeff

5 Arington, the president of Duramed; Bill Palmer,

6 John Neeley, and Bill Grunick from Viking.

7 Have you ever seen this document

8 before, sir?

9 A. I don't remember seeing this. Is it in my

10 documents?

11 Q. In your list?

12 A. Yeah.

13 I don't see it there.

14 Q. No. No; I don't see it either.

15 A. No, I haven't seen it.

16 Q. It's a breakdown, is it not?

17 In Exhibit 301 there is a breakdown

18 of HMO, formulary breakdown. And then there is a

19 breakdown of various MCOS and PBMs and their

20 formulary status; right?

21 A. Um-hum.

22 Q. And if you look at the page DUR10964 --

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1 A. Okay.

2 Q. -- there is a list of HMO formularies, and

3 there are totals at the bottom.

4 And the totals say that within HMOs

5 65 percent of the lives are in an open formulary, 11

6 percent of the lives are in three tier, and 24

7 percent are in closed formularies.

8 Do you see that?

9 A. Yes, I do.

10 Q. Do you have any information that any of

11 the HMOs that are listed in Exhibit 301 for which

12 Duramed has in its own documents that the formulary

13 status is open or three tier or closed -- do you

14 have any information that any of these are wrong or

15 incorrect?

16 A. Specifically?

17 I can tell you what I think; but I

18 cannot give you information that I know,

19 specifically, that these are closed.

20 Q. Well, I mean, I'm not asking you to guess.

21 A. Anything I would say -- for example, "John

22 Deere," that was not my understanding that they were

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1 open.

2 Other than that, no, I cannot -- this

3 could be true.

4 Q. In fact, "John Deere," sir, was a

5 situation where Cenestin was on formulary?

6 You didn't know that?

7 A. I did know that.

8 Q. Oh, you did know that. Okay.

9 A. But I didn't know it was an open

10 formulary.

11 Q. So when you say in your report that you

12 don't know why Duramed and Viking's contain these

13 figures -- you don't have any information that any

14 of these specific HMOs that are listed here, that

15 they aren't open or three tier or closed, as

16 indicated in this document?

17 A. I can tell you that when I look at this --

18 for example, where is PCS? It was on there.

19 Blue Cross/Blue Shield -- oh, using

20 PCS as their PBM.

21 So I can't tell you. No.

22 Q. Now, let's look at the PBM page -- which

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1 is the last page in the document, DUR10966.

2 All right. And here they have got --

3 they've gone through some of the PBMs -- "Advance

4 PCS," "Caremark," and others.

5 They've got 62 percent of the lives

6 being on open formularies, 30 percent three tier,

7 and 8 percent closed; do you see that?

8 A. Yes, I do.

9 Q. Do you have any information that any of

10 these PBMs that are listed here -- that this isn't

11 the situation for Cenestin?

12 In other words, do you have any

13 information to suggest that 62 percent of lives

14 within PBMs are not on open formulary as it relates

15 to Cenestin?

16 A. As it relates to Cenestin?

17 Now, you've -- you've thrown me.

18 What do you mean?

19 Q. Here's what I mean:

20 The testimony from the witnesses is

21 that these documents were prepared based upon

22 information received by Duramed and Viking -- from

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1 each of these managed-care organizations, as they

2 were looking at the situation for Cenestin.

3 A. I can tell you that if you look at the

4 first one, "Advance PCS" --

5 Q. Yes.

6 A. What does that mean? "MD"? The state?

7 So that means, within the state of

8 Maryland they have 33 million lives -- in the state

9 of Maryland, 33 million lives -- am I reading that

10 right?

11 Q. I think that the -- the state category --

12 again, this isn't a Wyeth document. This isn't my

13 document. This is a document from Duramed, who

14 you're working for.

15 I don't know the significance of the

16 state column. But we've got --

17 A. Well, I guess what I'm saying is that, you

18 know, just looking at the very first number has got

19 me concerned right away about the value of this --

20 of this report.

21 Q. But do you have any information -- all

22 right -- that any of these -- whether it's Advance

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1 PCS, where it says 75 percent of the lives are in  
2 open and 25 percent are in three tier for  
3 Cenestin -- that that's not correct?  
4 A. I can tell you that 50 percent of Advance  
5 PCS's business is in programs that they have a  
6 preferred list, a preferred category -- which you'll  
7 see in the tables that I've presented.  
8 50 percent of their book of business  
9 falls within that preferred category, where they  
10 actually call physicians, patients, and pharmacists  
11 for products that are not on formulary or on their  
12 preferred list.  
13 This document, to me -- if I'm  
14 looking at it and I see someone telling me there's  
15 33 million lives that PCS has in Maryland, I've --  
16 it goes to the problem with -- I mean, they claim 65  
17 million lives. Is half of it in Maryland?  
18 Q. No.  
19 Sir, I think all of these -- this is  
20 the -- where they believe that the -- that the --  
21 Caremark is headquartered in Illinois; right?  
22 Eckerd is headquartered in Florida.

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1 Express Scripts/DPS, is headquartered  
2 in Missouri.  
3 Do you see that?  
4 A. Um-hum.  
5 Q. And they've got 222 million lives. And  
6 we've got 62 percent are open, 30 percent three  
7 tier, 8 percent closed.  
8 And what I'm asking you is: Do you  
9 have any information, that you've seen anywhere,  
10 that supports the idea that that isn't what the  
11 situation was for Cenestin?  
12 A. Okay. So what --  
13 Q. See, what you have said is that, generally  
14 speaking, Advance PCS is, you know, 50 percent in  
15 preferred or whatever.  
16 I'm talking about for Cenestin,  
17 specifically.  
18 Do you have any information that any  
19 of these that are listed here by Duramed as open,  
20 that these are wrong?  
21 A. Do I have any information about these,  
22 individually or specifically, that they are wrong?

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1 Q. Yes, sir.  
2 A. I cannot say that any one of these  
3 particulars is wrong, because I don't have the  
4 information on the particulars.  
5 Q. Right.  
6 A. I can tell you that the "222 million" that  
7 they're totaling up to is wrong.  
8 Q. It should be higher?  
9 A. It should be much lower.  
10 Q. Which of these do you think is lower?  
11 A. Well, there are 240 million people in the  
12 United States that have health-care coverage;  
13 perhaps, 200 million that have a carve-out benefit  
14 for pharmaceuticals.  
15 This exceeds that entire population.  
16 Q. So there is some double counting?  
17 A. I don't know if it's double counting or  
18 what it is.  
19 Q. You're not familiar with the fact that  
20 some people -- if my wife, you know, works for the  
21 school system and she's got insurance -- and at my  
22 law firm, that we've got insurance -- that they'll

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1 both be counted.  
2 My plan might be through Aetna. Hers  
3 might be through Advance PCS.  
4 And that's why you get more than 240  
5 million Americans listed?  
6 A. I'm familiar with -- in PPO situations,  
7 that's correct.  
8 And you also have a situation where  
9 you may have a PBM and a mail order, and get counted  
10 twice.  
11 You may have -- and this is part of  
12 the problem with the data: You have PPOs for  
13 chiropractic, for podiatry, for dentistry, for  
14 everything else -- all of which could be included in  
15 these numbers.  
16 MR. DOBIE: You mentioned PCS. So  
17 let's just use that as an example.  
18 Why don't we mark this as the next  
19 exhibit.  
20 (Defendant's Exhibit Number 1079 was  
21 marked for identification.)  
22 MR. PARKER: I'm sorry. Where are

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1 we?

2 MR. DOBIE: 1079.

3 MR. PARKER: Okay.

4 BY MR. DOBIE:

5 Q. Mr. Simon, I've handed you what we've

6 marked as Exhibit 1079.

7 And just as an example -- all

8 right? -- you were talking about, at PCS, how you're

9 familiar with, you know, how much of the business is

10 typically in a preferred situation.

11 But look at that first paragraph.

12 Have you ever seen this Exhibit 1079

13 before?

14 A. Yes, I have.

15 Q. So you're familiar, then, that what Viking

16 was reporting is that Cenestin would be available at

17 the same co-pay level as products accepted for

18 inclusion in the 2000 formulary programs in at least

19 90 percent of their book of business or over 45

20 million lives.

21 Do you see that?

22 A. Yes, I do.

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1 Q. And so regardless of whether PCS's

2 situation may have been on how they handle all their

3 other products, are you aware that Viking called on

4 PCS and PCS made the decision to reimburse Cenestin

5 like Premarin, even though it wasn't on formulary

6 for 90 percent of their book of business?

7 A. I am familiar with that.

8 Q. And there's other examples as well.

9 You've got -- with -- if you look at

10 the next page, there's a discussion about "United

11 Healthcare." That's a big HMO. 44 regional plans

12 across the country.

13 Cenestin -- in the second paragraph,

14 it states that Cenestin is considered non-formulary,

15 however is being reimbursed in the majority of their

16 plans at the \$13 co-pay.

17 Do you see that?

18 A. Um-hum.

19 Q. And if you look at -- I don't know. I

20 mean, we can go through these.

21 Strike that.

22 What I'm getting at, sir, is:

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1 When you say that you don't know why

2 Duramed's figures contain these figures of 60 to 70

3 percent -- all right, I understand you haven't read

4 all the depositions -- or any of the depositions

5 beyond Mr. Williamson's and Mr. Kolassa's -- but you

6 don't have any information -- do you? -- that

7 suggests that the numbers that are provided in

8 Exhibit 301 are incorrect?

9 A. The data that I have provided from the

10 audited -- from the audit sources -- this is not

11 possible to be true, if the data that I have

12 presented is true or the data that Wyeth has

13 prepared in their research is true.

14 Q. Well, let me ask you about the data that

15 you presented.

16 And you mentioned first the Novartis

17 and the Wyeth information. So let's look at that.

18 A. "Novartis"?

19 And that's the very next page.

20 Q. Right.

21 You've got it summarized in your

22 report. Okay?

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1 A. It isn't the easiest thing to read,

2 though.

3 Q. The Novartis data?

4 A. "Novartis"; right.

5 Q. "Novartis."

6 Okay. Looking at your table on page

7 8, this only relates to HMOs; right?

8 A. This only relates to HMOs.

9 Q. And HMOs are -- what? -- 30 percent of the

10 insured marketplace in 2000?

11 A. No; they're bigger.

12 The difference between HMOs and PPOs

13 is that PPOs get counted multiple times. HMOs

14 represent something in the neighborhood of 100 --

15 now, I believe, it's like 110 million lives.

16 Q. At the time of the data that's here, 2000

17 HMO --

18 A. 100 million lives.

19 Q. You think that's 100 lives?

20 A. Yes.

21 Q. You think that the data, the 2000 HMO --

22 the data represents 100 million lives?

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1 A. Correct.

2 Q. All right. Now, that Novartis study --

3 they don't actually go out and survey all of the

4 HMOs, do they?

5 A. No.

6 Q. All right. They go out; and they survey a

7 portion, a sample. Right?

8 A. They're an audit.

9 Just like IMS, they go out and use

10 the same -- as a matter of fact, they use -- the

11 audit source that this comes from used to be owned

12 by IMS. So they apply the same kind of statistical

13 routines to find out how many people they need to go

14 talk to, to make it representative of the nation.

15 Q. All right. And the table that you've

16 prepared here is a summary of the Novartis data;

17 correct?

18 A. It actually comes directly from their

19 report.

20 Q. And what you have listed here, just to

21 sort of walk through -- you've got the co-payment

22 design, whether it's a one tier or multiple tiers.

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1 And then you've got it broken down

2 into commercial group. I guess that's insured,

3 Medicaid, Medicare, and overall.

4 Right?

5 A. Correct.

6 Q. Now, the Medicaid and Medicare portion of

7 the chart -- let's just start with that.

8 No restrictions by Wyeth, no

9 contracts that prevented Cenestin from competing in

10 any way in the Medicaid or Medicare market; right?

11 A. Correct; except in the selective and

12 partially selective categories -- in the partially

13 selective category of business.

14 However, they're all one tier. So

15 the fact is that, no, there was no detriment.

16 Q. So we're talking, really, about the

17 commercial group, then.

18 A. Well, actually, we're talking about the

19 overall.

20 Q. All right. So, you want to talk about the

21 overall. That's fine.

22 A. Well, no. The point is: Medicare and

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1 Medicaid do not represent -- and I didn't put on

2 this chart, you know, who's responsible for what.

3 You're right. The commercial group

4 would certainly be the biggest portion of their

5 business.

6 But to really get the assessment of

7 HMOs, the overall is the way to look.

8 That's what I look at.

9 Q. That's fine. If you want to look at

10 overall, that's fine.

11 And what you've done is: You've said

12 that the portion that's open within HMOs, you've

13 combined the first and -- the one-tier and the

14 two-tier formularies within the open group; right?

15 A. Correct.

16 Q. All right. And then in the three-tier,

17 you're assuming -- right? -- if you look here, that

18 33 percent -- you're assuming that, within HMOs,

19 Cenestin is not -- is not reimbursed in the

20 second-tier category; right?

21 A. I'm not assuming anything about Cenestin

22 in this report.

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1 Q. Okay.

2 A. I'm just presenting: This is the

3 marketplace as the marketplace exists in HMOs.

4 Q. All right. But what I'm interested in --

5 and that's fine -- you're not suggesting in this

6 report, Mr. Simon, that if we were to look at the

7 underlying data from Novartis and look at who are

8 the HMOs that are reporting -- that even though they

9 might have 33 percent of their lives in a three-tier

10 formulary, that there wouldn't be HMOs within that

11 that have put -- that are still reimbursing Cenestin

12 in the second tier; right?

13 A. I'm sorry. I'm having difficulty

14 following.

15 What I am saying is: This is what

16 the marketplace looks like. It does not necessarily

17 represent where Cenestin falls within this

18 marketplace.

19 Q. Okay.

20 A. Is that your question?

21 Q. Yes. Yes. Okay.

22 And an example would be -- maybe, we

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1 were just looking before at Aetna.

2 Aetna is -- where was it, here? We

3 were looking at Exhibit 1079.

4 You know, 1079 says: At this time,

5 while no contract exists with Aetna, Cenestin will

6 not be included in their drug formulary.

7 So, again, it wouldn't be in the

8 second tier; but for the majority of Aetna's plans,

9 Cenestin will be covered and reimbursed at the

10 standard co-pay level and not actively intervened

11 against.

12 In other words --

13 A. That's what he's saying.

14 I don't know that.

15 Q. Right.

16 But this table that you've put

17 together here, it's not -- you haven't attempted to

18 bring in Cenestin, specifically, and whether it fits

19 into the -- whatever fit in -- or where it would fit

20 within the table?

21 A. That's correct.

22 Q. Now, on one of the other documents that

1 here that this data comes from currently tracking

2 276 regional HMO/PPO targets for Cenestin

3 reimbursement status.

4 Do you see that?

5 A. Um-hum.

6 Q. Do you know who those 276 regional HMOs

7 are?

8 A. No.

9 Q. All right. Do you have any reason -- I

10 mean, so you're not in a position to say that -- or

11 to know whether or not those 276 regional HMO/PPOs

12 are any different -- are the same or different than

13 the HMOs that are listed in Exhibit 301 that we were

14 looking at before?

15 A. No, I don't.

16 Ask the question again. I'm not

17 sure.

18 Q. Here's what I'm getting at:

19 These HMO/PPO targets, regional

20 targets -- these could be things like, you know, the

21 United Auto Workers, the American Airlines health

22 plan. It could be things like that.

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1 you mentioned, you talk about the documents that may

2 have gone the other way, in terms of how much is

3 open; and I want to show you some of those just to

4 make sure we're on the same page there.

5 I hand you what we marked as Exhibit

6 16.

7 Okay. And for the record, Exhibit 16

8 is the "2000 Business Plan, Cenestin Tablets," July

9 2000, from Mike Williamson of Solvay.

10 Sir, this is one of the documents, I

11 think, that's on your --

12 A. I've seen this.

13 Q. You've seen this one. All right.

14 And if you look at page DUR29313,

15 this is the -- some of the data that you were

16 talking about that had Cenestin's reimbursement

17 status --

18 A. Yes.

19 Q. -- as being less than 60 to 70 percent --

20 A. Yes.

21 Q. -- as referenced by Dr. Kolassa?

22 Now, let me ask you this: It says

1 It might not be -- we don't know,

2 looking at this data here, who these 276 regional

3 HMOs are; correct?

4 A. I don't know who they are.

5 I've got to make an assumption that

6 they are not going to be out chasing ether in a

7 marketing plan. I mean, they're not going to put a

8 plan together that says: I want my sales reps to go

9 to these plans that don't matter.

10 So, yeah, I make that assumption that

11 they're in the business to go out and sell the

12 product.

13 Q. Well, do you know to what extent Solvay

14 called on managed-care plans, as it relates to

15 Cenestin?

16 A. No, I do not.

17 Q. Do you know whether or not they did at

18 all?

19 A. I believed that I've read some places

20 where they have indeed called on managed-care

21 customers.

22 Q. As it relates to Cenestin?

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1 A. Solvay.  
2 Q. Solvay?  
3 A. Yes.  
4 Q. Okay.  
5 A. But -- but I'm -- I'm -- I'm not sure.  
6 Q. All right. And then on the next page,  
7 where it says "Corporate Targeted Accounts."  
8 A. Correct.  
9 Q. And again, do you know who those  
10 "Corporate Targeted Accounts" would be?  
11 A. No.  
12 You know, when you asked me that  
13 question about Solvay calling on managed-care  
14 accounts -- I don't see how they could avoid talking  
15 about Cenestin, when they're already in those  
16 offices talking about other products that they --  
17 that they promote and they have their own  
18 managed-care department.  
19 Q. You think the natural thing would have  
20 been to have Solvay call on managed care?  
21 A. I think that Duramed did the right thing  
22 in bringing Viking in before they launched a product

1 Solvay the product to promote in managed care -- and  
2 then they never called on managed care for that  
3 product -- would it make a difference?  
4 I don't know if that's your question  
5 or not; but if that is, then I think the answer is:  
6 Definitely, it would make a difference. Someone  
7 needs to call on managed care.  
8 Q. Right.  
9 And so in other words, if Solvay was  
10 only promoting its products, as opposed to Cenestin,  
11 when it called on managed care -- that could have  
12 hurt the uptake of Cenestin?  
13 A. If they didn't have Viking calling on  
14 them?  
15 Q. I want to back up.  
16 You said a minute ago that you think  
17 it would have been natural for Solvay to have been  
18 promoting Cenestin --  
19 A. No --  
20 Q. -- to managed care.  
21 A. -- that's not what I said.  
22 What I said -- I hope I didn't say

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1 to get them prepared to do it, because the agreement  
2 with Solvay never happened until -- what? --  
3 October.  
4 So there was no signed agreements  
5 until October. They couldn't rely on Solvay.  
6 Q. Do you think that it would be appropriate  
7 to have had Solvay calling on managed care?  
8 A. Do I think it would be appropriate? I  
9 think it would be something I'd want to investigate  
10 a year out, or so, after -- you know, when I was  
11 preparing my next marketing plan.  
12 Would it be something that I would  
13 consider?  
14 Q. Yes.  
15 A. Yes, I would consider it.  
16 Would I do it? It depends.  
17 Q. Do you think that Cenestin might have been  
18 impacted by -- or received fewer formulary approvals  
19 if Solvay was only promoting its products for  
20 formulary inclusion, as opposed to Cenestin?  
21 A. Let me see if I understand this correctly.  
22 If you're asking me if I would award

1 that -- what I thought I said was:  
2 It would have been natural for Solvay  
3 to hear about Cenestin while they're in there  
4 talking their other products.  
5 If the managed-care company,  
6 whoever -- Aetna -- whoever -- if they're calling on  
7 them for another product that they're manufacturing  
8 at Solvay and -- it would be just natural, I would  
9 imagine, for the purchaser to say, "How is Cenestin  
10 going? Why aren't you guys selling it?"  
11 I mean, I could see that come up.  
12 Q. But you don't know that that happened?  
13 A. But I absolutely do not know that that  
14 happened.  
15 Q. In fact, it could just as well be likely  
16 that they were forbidden from talking about Cenestin  
17 when they went in?  
18 A. It very well be that they were forbidden  
19 to talk about it.  
20 That doesn't mean that you don't hear  
21 things.

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1 A. But, yes.

2 Q. You don't know whether that happened, one

3 way or the other?

4 A. Do not know that.

5 Q. And then on page 9 of your report, you

6 talk about how Wyeth personnel report that Duramed's

7 access to managed care has been restricted by

8 Wyeth's contracts.

9 And you reference some documents at

10 the bottom of the page that refer to Express Scripts

11 and Medco.

12 So I assume you're familiar with the

13 situations with both?

14 A. (Witness nods head.)

15 Q. You have to respond verbally.

16 A. Yes.

17 Q. All right. And you understand that the

18 exclusive contract -- exclusive, sole,

19 conjugated-estrogen contract with Express Scripts

20 only related to the non-bid-grid portion of Express

21 Scripts' business?

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1 Q. Did you know that?

2 A. I was not aware that there was a

3 significant difference between the two.

4 Q. Do you know whether or not, within that

5 portion of the business, it's almost 100 percent

6 open formulary?

7 A. And how much -- well --

8 Q. Within the --

9 A. No, I didn't know.

10 Q. How about with Medco; do you know what

11 percentage --

12 A. Now, wait. We're talking -- you were

13 talking Express Scripts.

14 Q. Yeah. Now let's switch to Medco. Let's

15 talk about Medco for a little bit.

16 A. Wait. Let's stay on Express Scripts,

17 because my understanding was that they had a

18 bid-grid contract with MedImpact.

19 Is that what you were referring to?

20 Q. No. I was talking about Express Scripts.

21 A. I'm talking Express Scripts too.

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1 A. But there was a process that they went

2 through, that -- this "bid-grid" thing that you're

3 talking about -- where Cenestin was put on, but that

4 it was subsequently removed as a result of

5 discussions with Sally Miller or -- am I on target?

6 Q. That's it. That's the Express Scripts

7 1999 bidding for the 2000 formulary bid grid.

8 A. So my answer to that is: Yes, I am

9 familiar with that.

10 Q. And you also know that on the bid-grid

11 side that Cenestin went on formulary in 2001; right?

12 A. I didn't review 2001, no.

13 Q. How about at Medco; do you know, within

14 the estrogen category, how open the Medco plans are?

15 A. In the ERT category, no, I do not.

16 Q. So it could very well be that, although

17 Wyeth and Medco contracted, that Wyeth would be the

18 sole conjugated estrogen -- that, within Medco,

19 Cenestin would be reimbursed at the same co-pay --

20 assuming it's, let's say, 90 percent open?

21 A. Say that again, because I am -- this is

22 not my understanding that they're anywhere near 90

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1 percent open, especially with their mail-order

2 business.

3 Q. They didn't provide you with the documents

4 relating to the --

5 A. They may have, but it may have been detail

6 that I did not get.

7 Q. Mr. Simon, then, you're not familiar with

8 what portion of Medco lives are in an open-formulary

9 situation?

10 A. That's correct. I am not familiar with

11 how many are in an open situation.

12 Q. So you're not able to say, with Medco, to

13 what extent Cenestin -- you're not able, then, to

14 say, within the Medco lives, to what extent Cenestin

15 was disadvantaged?

16 A. Within the Medco lives, no, I can't say if

17 it's 1 percent or 100 percent.

18 Q. Now, let's talk about Medi-Span.

19 On page 9 of your report, you say

20 that restrictions on 30 to 40 percent of the market

21 is sufficient to seriously affect Cenestin's sales.

22 Let me start off first with that.

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1 You note that if Cenestin was  
2 excluded from 30 to 40 percent of managed-care  
3 lives, that this could still sufficiently be  
4 restrictive -- to result in decreased Cenestin  
5 prescriptions by physicians.  
6 I want to ask you first about the  
7 "if."  
8 You're assuming, for purposes of the  
9 report, that that might be the number; but you don't  
10 know?  
11 A. I'm -- I'm saying that, even if you're  
12 correct or even if Dr. Kolassa -- or whatever the  
13 number is -- 60 to 70 percent of lives were open,  
14 this still would be a difficult situation.  
15 Q. What if it was 60 percent open and then  
16 another 30 percent in three tier -- like what we  
17 were looking at -- I think it was 24 percent, three  
18 tier, as indicated in Exhibit 301 -- but in fact,  
19 the product, because Cenestin has a low cash price,  
20 was being reimbursed in second tier?  
21 A. I did not evaluate the impact.  
22 Q. Now, tell me about Medi-Span.

1 Besides that, there are other  
2 individuals that you talk to to find out their  
3 interest in the product as well.  
4 And that would be the software  
5 companies that are providing physician  
6 practice-management software, the fact that they  
7 would talk to their physicians and get that input  
8 and give that same input to you.  
9 Q. And what you're saying is that, based upon  
10 talking to somewhere between 12 and 24 physicians,  
11 you can say that for a drug to be disadvantaged by a  
12 third of the doctor's managed-care patient load is a  
13 significant disadvantage?  
14 A. I'm saying that, based on the things that  
15 are in here and that I was told --  
16 Q. Right.  
17 A. -- by those individuals, it would  
18 definitely be detrimental to the product.  
19 Q. But you're not saying that a product  
20 couldn't succeed -- products like Lescol and others  
21 that have succeeded without a formulary placement --  
22 right?

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1 And you mention that you were out  
2 there talking to doctors and trying to determine to  
3 what extent a computerized formulary software  
4 package might be something attractive to physicians.  
5 And you told me that it was something  
6 that ultimately wasn't marketed. The company was  
7 sold.  
8 When you talked to physicians, did  
9 you do a statistical analysis, anything like that?  
10 A. No. No, sir.  
11 Q. What was the number of physicians that you  
12 talked to about the computerized formulary software?  
13 A. Oh -- I can't remember. It's certainly  
14 going to be less than 24 and more than 12.  
15 Q. Okay.  
16 A. Now, that's physicians.  
17 Q. Yes.  
18 And then, how do you generalize from  
19 a sample that small?  
20 A. When you get the same answer from  
21 everybody, it's pretty -- pretty conclusive that  
22 that's what's happening.

1 You're not disputing that?  
2 A. I'm not saying that a product can't  
3 succeed, like a Celebrex -- which was on prior  
4 authorization.  
5 But I'm also -- when you're talking  
6 about a Celebrex, you're not talking about a product  
7 like this. You're talking about a brand-new  
8 category, etc.  
9 Yes; you're right.  
10 MR. DOBIE: Let's take a -- see if  
11 that lunch is -- they might have just stuck it  
12 next door -- because I'm kind of hot in here  
13 too, I'll be honest with you.  
14 VIDEOGRAPHER: The time is 12:55.  
15 We're off the record.  
16 (Whereupon, at 12:55 p.m., a lunch  
17 recess was taken.)  
18  
19  
20  
21  
22

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AFTERNOON SESSION

(1:24 p.m.)

VIDEOGRAPHER: The time is 1:24.

We're back on the record.

BY MR. DOBIE:

Q. Mr. Simon, I wanted to visit with you about the section of your report that's Roman numeral V, Duramed's marketing program.

And you say that the -- do you have it, page 11 -- that the original market plan that was prepared by Duramed in 1998 is what would be expected from a small manufacturing company.

And there is a -- you know, a few places where you reference the fact that the marketing program was about what you'd expect for a smaller company.

I'm just wondering what you meant by that.

A. Well, when you market a product, you -- there are going to be certain things you're going to do:

You're going to go to the market.

product -- a product with \$100 million in sales rather than, let's say, 10- or 20-million dollars in sales -- don't you think you need to undertake the promotion like the bigger companies?

A. I think if you're looking to achieve a 6 percent share of the marketplace that's available to a product, you are looking to do things that you wouldn't normally do if you were looking to come out with something that was a ground-breaking or earth-shattering kind of a product.

If you're going into a class like -- like this and looking for a 6 percent marketshare, I think that they did plenty -- sufficient.

Q. Well, when you're talking about a 6 percent marketshare in a product that the entire category is, let's say, \$100 million -- that's one thing.

But this one, a 6 percent marketshare -- they were looking for \$100 million in sales; right?

A. Um-hum. Um-hum.

Q. And don't you think that you need to

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You're going to do your market research. You're going to talk to your customers and find out what kinds of things were important to them.

Then you're going to try and develop a strategy, and have a lot of meetings internally and put together an appropriate message, based on the strategy, and go to the market with that message.

You're also going to look at what kind of sales force you need in order to reach that market.

All of the things that are required to bring the product to the marketplace they did.

Now, if I were launching a product like Cenestin -- and I know I probably shouldn't be getting into Cenestin -- but when you're marketing big, big products you have big, big budgets. And you would probably do a lot more research and things like that.

Q. Well, do you think if you're trying to -- I understand it's a small company.

But if you're trying to have a big

spend, you know -- or don't you think most companies, to achieve \$100 million in sales, just in their first year, that they would --

A. I don't think that's what it said.

Q. You didn't see the projections that they made?

A. The projections that I saw?

Q. Yes, sir.

What projections did you see?

A. I was under the impression that Mr. Arington had presented to Wall Street and others that, at the end of 18 months -- and I believe that's what was in Dr. Kolassa's report -- they would be at \$1 million pace.

Q. Or \$150 million pace; right?

A. 100- to 150-, maybe.

But the \$100 million pace is what I was led to believe.

Q. And do you think that most companies, to get to a \$100 million a year pace, would have to spend -- on promoting the product, on marketing the product -- \$100 million in that first year?

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1 A. Absolutely not.

2 And I don't think that you would find

3 a major company that would even launch a blockbuster

4 at that level.

5 Q. You're not aware of anything in the

6 literature, anything within your experience that

7 would suggest that you would need to spend that kind

8 of money in order to get those sales?

9 A. That I would need to spend 100- to

10 150-million dollars?

11 Q. Yes, sir.

12 A. In order to get \$100 million?

13 Q. Yes.

14 A. No.

15 Q. So where Dr. Kolassa says that the rule of

16 thumb in pharmaceutical marketing, that a company

17 would expect to spend 100 to a 150 percent of

18 expected first-year annual sales on promotion -- is

19 certainly not a rule of thumb in any of the

20 companies where you worked?

21 A. That's correct.

22 Q. And not only wasn't it a rule of the thumb

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1 in the companies where you worked, but you're not

2 aware of that being true in the industry, generally?

3 A. I am not aware of that being true in the

4 industry.

5 Q. And did you do any research to look and

6 see whether or not Dr. Kolassa was --

7 A. In fact, I did.

8 I went back and looked at the -- some

9 of the documents that he prepared or used in his

10 documentation.

11 And the information that I got was

12 that companies, for launching of a blockbuster,

13 might spend -- and a "blockbuster" here means

14 billion dollars plus -- they would perhaps spend 500

15 million in the five years leading up to and

16 including that first year.

17 Now, that doesn't equate to 100

18 percent.

19 Q. What are you referring to?

20 What documents are you referring to?

21 A. I believe it's in the document about

22 launching a blockbuster.

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1 I do not remember what the numbers or

2 anything like that are, but I believe it's in that

3 document.

4 Q. Now, you have been tendered by Duramed as

5 an expert in pharmaceutical marketing.

6 You understand that?

7 A. Correct.

8 Q. And you understand that Duramed also has

9 another expert by the name of "Steven

10 Schondelmeyer," and he has also given an expert

11 opinion on marketing issues?

12 A. I'm aware that Steven Schondelmeyer is

13 involved. I don't know what his -- you know, what

14 he has been requested to do.

15 Q. You've never reviewed his report?

16 A. No, I have not.

17 MR. DOBIE: Why don't we mark this as

18 the next exhibit.

19 (Defendant's Exhibit Number 1080 was

20 marked for identification.)

21 MR. DOBIE: For the record, Exhibit

22 1080 is a copy of a document from the U.S.

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1 Congress, Office of Technology Assessment,

2 "Pharmaceutical R&D: Costs, Risks, and

3 Rewards."

4 BY MR. DOBIE:

5 Q. Have you ever seen this document before,

6 sir?

7 A. I don't think so.

8 Q. Well, look at page "v."

9 That's the fifth page in.

10 A. Okay.

11 Q. There is like a "v" there.

12 And there is a list of principal

13 contractors. And you see "Steven Schondelmeyer" is

14 listed as one of the principal contractors, over on

15 the top of the right-hand side?

16 A. Yes, I do.

17 Q. All right. Let me ask you to turn to page

18 90.

19 It says: "Pharmaceutical R&D:

20 Costs, Risks and Rewards."

21 A. Okay.

22 Q. And in the column that is on the left-hand

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1 side, it says: "Cost of Manufacturing, Marketing,  
2 and Distributing NCES."  
3 Do you see that?  
4 A. Um-hum. Yes, I do.  
5 Q. And that has to do with new --  
6 A. -- chemical entities.  
7 Q. -- new chemical entities. All right.  
8 And if you look down here, it says:  
9 The office of technology  
10 assessment -- this is in the paragraph at the bottom  
11 of the line, the bottom of the page -- estimated  
12 manufacturing, distribution, marketing, and  
13 administrative costs from a variety of sources,  
14 including the existing literature and annual reports  
15 of six U.S. companies, with pharmaceutical sales  
16 comprising at least 65 percent of total company  
17 sales.  
18 Do you see that?  
19 A. Yes, I do.  
20 Q. And it says in the next paragraph:  
21 Marketing costs were assumed to be  
22 higher in the early years of product life and low

1 Q. And for Year 2, "50.0% of sales"?  
2 A. That's what it says.  
3 Q. So you'd agree with me that at least the  
4 U.S. Government has concluded that, on average,  
5 pharmaceutical companies were spending 150 percent  
6 of their sales on marketing during the first, at  
7 least, two years of the launch of the product?  
8 A. No, I don't agree.  
9 I agree that, for the six firms that  
10 they looked at -- which were Merck, Eli Lilly,  
11 Syntex, Schering-Plough, Upjohn, and Pfizer -- that  
12 that may be the truth.  
13 Q. Okay.  
14 A. And I can assure you that that would be  
15 based on the type of product and the duration of  
16 their patents for these products, as well.  
17 Q. But your statement in your report that  
18 there is -- that you're not aware of anything --  
19 anything -- that one would expect to spend 100 to  
20 150 percent of expected first-year annual sales on  
21 promotion -- when you wrote this, sir, you weren't  
22 aware of the government's report; right?

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1 after patent expiration; but over the lifetime of  
2 the product, they averaged 22.5 percent of total  
3 sales.  
4 Right?  
5 A. That's what it says.  
6 Q. And look at the next page, if you would.  
7 There's a table that has the cost  
8 assumptions in the office -- the government's Office  
9 of Technology Assessment's analysis of returns on  
10 R&D.  
11 And if you go down four lines -- one,  
12 two, three, four -- marketing costs is a percentage  
13 of sales.  
14 Do you see that?  
15 A. Oh, up here?  
16 Yes.  
17 Q. It's in the table.  
18 A. Yes.  
19 Q. And Year "1" --  
20 A. Um-hum.  
21 Q. -- it says "100.0% of sales"; doesn't it?  
22 A. That's what it says.

1 A. I was not aware of this report; and I  
2 still -- I still would want to look a lot more  
3 detail of this and what type of drugs they're  
4 talking about, because I know that it costs almost  
5 \$800 million -- or at least that is what the  
6 Pharmaceutical Manufacturing Association says -- to  
7 bring a product to market.  
8 Well, if I'm going to invest \$800  
9 million in a product that's going to come to market,  
10 I'm going to be launching a product that has  
11 blockbuster potential and I'm going to invest very,  
12 very heavily in it.  
13 This product, they were looking at a  
14 6 percent marketshare in a market that was -- has  
15 been around.  
16 Q. So your view is, is -- if you're looking  
17 for only a 6 percent marketshare, that you don't  
18 need to spend money that would approach these  
19 figures?  
20 A. I'm saying that, if you are looking to  
21 achieve a 6 percent marketshare, you're not going to  
22 spend the same money as you would trying to achieve

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1 a 50 percent marketshare.  
2 Q. Well, let me ask you this --  
3 A. Does that make sense?  
4 Q. -- can you name for me one \$100 million  
5 product that was launched without spending at  
6 least -- I'm sorry -- one -- strike the question.  
7 Can you name for me one product that  
8 got \$100 million worth of sales in its first year,  
9 that was launched without spending \$100 million in  
10 marketing?  
11 A. Absolutely can not.  
12 And by the way, this product wasn't  
13 looking to do 100 million in its first year.  
14 Q. Well, in 18 months, can you name one  
15 product that was going to do 100 to \$150 million in  
16 sales in 18 months that didn't spend 100- or  
17 150-million dollars in marketing?  
18 A. No, I can't.  
19 You mean, branded products, now --  
20 I'm assuming?  
21 Q. Any product. Any pharmaceutical product.  
22 A. I would have to think about this, but

1 A. No.  
2 Q. Have you ever attended meetings of the  
3 Pharmaceutical Marketing Congress?  
4 A. I may have attended one.  
5 Q. When was that?  
6 A. And I can't -- back in the mid-'90s, early  
7 '90s.  
8 Q. What is "share of voice" in the  
9 pharmaceutical industry?  
10 What does that mean, "share of  
11 voice"?  
12 From a pharmaceutical marketing  
13 standpoint, what does that mean: "share of voice"?  
14 A. Well, "share of voice" is looking at all  
15 the things that are going -- all the promotion  
16 that's going out to the physicians' audience and  
17 looking at your competitors.  
18 And there's two ways of looking at  
19 it: There's share of voice, and then there's  
20 relative.  
21 And what you're looking at is: Of  
22 all the promotional messages and dollars being spent

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1 there's a couple of products that come to mind that  
2 could have approached that.  
3 Q. What are those products?  
4 A. Clonazepam, for one -- which was a generic  
5 launched by itself.  
6 Marketing, probably -- marketing  
7 costs at 1 or 2 percent.  
8 Q. Right. So a generic, you don't have to  
9 market. That gets automatically switched.  
10 A. I agree.  
11 Q. Okay.  
12 A. But that's why I asked you the question.  
13 Q. I understand.  
14 So with a branded -- the way you were  
15 trying to get me to revise the question is correct.  
16 You can't think of any branded  
17 pharmaceutical product that got 100- or 150-million  
18 dollars in sales without spending 100- to  
19 150-million dollars on marketing?  
20 A. Off the top of my head, I cannot.  
21 Q. Now, are you by any chance a member of the  
22 Pharmaceutical Marketing Congress?

1 to provide messages to the audience, what is your  
2 share -- or what percentage of all of that message  
3 is coming from your product?  
4 A long-winded answer.  
5 Q. Well, does that include, for example,  
6 detailing physicians?  
7 A. That would include detailing.  
8 Q. How about direct-to-consumer advertising?  
9 A. That would include that.  
10 It would include journal  
11 advertisements.  
12 Q. Okay. Now --  
13 A. And depending on what kind of company you  
14 are, it could include other things -- because you  
15 can look at this differently for different  
16 companies.  
17 Q. Now, you mention that you might spend less  
18 money if all you wanted was a 6 percent marketshare.  
19 Let me ask you this: Do you know  
20 what Duramed's share of voice was in 1999, 2000, or  
21 2001?  
22 A. I saw the statistics. I don't know them

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1 off the top of my head.

2 Q. About 8 percent or so, at the high end?

3 A. If that's what you say.

4 I -- I honestly don't remember.

5 Q. Would you agree with me that there is a

6 correlation between the share of voice and how a

7 product will do, a branded pharmaceutical product

8 will do?

9 A. I would love to say yes, because it's an

10 easy answer.

11 But the answer is: If you're giving

12 a message that's bad, the answer is no. If you're

13 giving a message that has meaning to it, that

14 doctors perceive as being valuable, then the answer

15 is yes.

16 If your competition is not giving the

17 same quality of call, let's say -- if you're giving

18 details in the first position which may come in, in

19 terms of share of voice, at the same cost as a

20 Detail No. 2 or 3 -- I guess what I'm trying to say

21 is: You can't go, based on a -- one global

22 number -- and say, "This is going to make the

1 numbers, share of voice. And they talk about what's

2 going on and how the product has managed to get from

3 one place to another over time.

4 It really depends on the kind of

5 product, the kind of marketplace that you're in, the

6 kind of market -- you know, your competition -- all

7 those things.

8 MR. DOBIE: Why don't we mark this as

9 the next exhibit.

10 You mentioned "IMS." Let me show you

11 a document.

12 What are we on? 10 -- 1081.

13 (Defendant's Exhibit Number 1081 was

14 marked for identification.)

15 MR. DOBIE: For the record, Exhibit

16 1081 is a copy of a document produced by IMS on

17 October 6, 2002, and presented at the

18 Pharmaceutical Congress meeting.

19 BY MR. DOBIE:

20 Q. And, sir, have you ever seen this document

21 before?

22 A. This, no.

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1 difference," because that just isn't the case.

2 If you have a cure for AIDS, guess

3 how much you would have to put in the marketplace to

4 sell it? You wouldn't need any share of voice.

5 And that's -- believe me, I mean,

6 that's really an extreme example. But, hopefully,

7 I'm getting across what I mean.

8 Q. Are you aware of any product that has ever

9 obtained, let's say, 10 percent of the marketplace

10 without having a 30 percent share of the voice?

11 A. I haven't investigated that.

12 Q. Okay.

13 A. And I'm assuming, again, you're talking

14 brands?

15 Q. Yes.

16 Okay. How about, have you ever

17 looked to see whether or not you would have to have

18 some percentage of share of voice to obtain what you

19 said: 6 percent of the marketplace?

20 A. Here again -- I mean, IMS goes out and

21 they make presentations every year.

22 And they give -- they give these

1 Q. Have you heard of the publication of this

2 information within the pharmaceutical marketing

3 community?

4 A. This specific?

5 Q. Yes, this study that they did.

6 A. No; I'm not aware of this.

7 Q. So there was a 600-person congress of the

8 Pharmaceutical Marketing Congress, where this was

9 announced --

10 A. No. This was just presented five days

11 ago.

12 Q. All right.

13 The IMS, as you mentioned before,

14 they collect data on every -- on pharmaceutical

15 products and every prescription that's written;

16 right?

17 A. No. They collect a sample the same way

18 the data was prepared for the Novartis audit.

19 They have a sample of data that they

20 capture prescription information on.

21 They do sell information that

22 captures the sale, the actual transfer of product --

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1 Q. Right.

2 A. -- from one place to the next. But they

3 don't capture every prescription.

4 Q. Every sale.

5 Now, the study revealed that

6 throughout the 1990s no product has ever achieved at

7 least 5 percent of sales without a 20 percent share

8 of voice. Not one.

9 A. It's never -- say that again.

10 Q. No pharmaceutical product has ever

11 achieved even a 5 percent share of market without 20

12 percent of the share of voice.

13 A. Share of voice; okay.

14 MR. PARKER: Where are you in the

15 report?

16 MR. DOBIE: Look at -- look at page

17 18.

18 Q. So if you look at page 18 --

19 A. I'm getting there.

20 Sorry. I'm slow, but sure.

21 All right. I'm on 18.

22 Q. And if you look, you can see that they've

1 A. Okay.

2 Q. -- or less, depending on the year --

3 okay -- isn't it true that its sales are about what

4 one would expect?

5 Wouldn't you agree with that, based

6 on this data?

7 A. No, not at all.

8 Q. With all of the problems with this

9 product, with its indications, with everything that

10 we've talked about, and with the share of voice

11 being below everybody else in the -- strike that.

12 Why do you think that Cenestin would

13 be so much better than every other pharmaceutical

14 product that has been launched in the last 12

15 years -- that their sales would have been 6 percent,

16 when its share of voice was 8 percent and the money

17 that it spent on promotions was a fraction of what

18 is typically spent according to the U.S. Government?

19 A. I think that you are making some real

20 interesting assumptions.

21 First off, when I look at this data,

22 this is saying: At the end of a year, this is what

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1 got Year 1 prescription share.

2 And then you've got Year 1

3 professional promotion share of voice.

4 And you can see here that nobody is

5 over a 5 percent marketshare unless their share of

6 voice exceeds 20 percent; right?

7 A. That's what they're showing.

8 Q. And --

9 A. But out of curiosity or maybe -- maybe --

10 I don't know if this needs to be reiterated now.

11 A 5 percent share over -- at the end

12 of one year of sale is not the same as a 5 percent

13 share going into the next year.

14 A 5 percent share, starting at zero,

15 perhaps means you've got a 10-, 12-, 15 percent

16 share that -- on Month 12 of that product.

17 So, I mean, this may well be true.

18 But it's not -- we're comparing apples and oranges.

19 Q. Well, here's what I'm getting at:

20 All right?

21 If Cenestin's share of voice was 8

22 percent --

1 their share of sales are --

2 Q. Right.

3 A. -- which, like I said, may be -- I don't

4 know. It could be that they are at a 20 percent

5 share at Month 12, in order to accomplish this sale

6 during the year -- because they start at zero.

7 Q. Well, look at the next page. Okay.

8 A. Well, I looked at -- frankly, I looked at

9 some of the earlier pages and what they talk about,

10 pre-launch scenarios.

11 Here's a sales force with 800

12 representatives. Guess what? I would probably be

13 willing to bet you those are the companies whose

14 products fall within this category.

15 Now, I don't know if I'm making sense

16 or not --

17 Q. In other words, if they have 800 reps,

18 more likely that they're going to be above the 5

19 percent --

20 A. That's what the report is saying.

21 Q. Right.

22 So the more you spend -- and -- I

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1 mean, I don't think we're disagreeing, Mr. Simon.  
2 We began the deposition; and you told  
3 me that the single, most important thing that has to  
4 do with the success of a product is the detailing,  
5 the sales forces behind it.  
6 A. The salespeople, exactly.  
7 Q. And this document is consistent with that,  
8 isn't it?  
9 A. Well, with -- with that statement, I  
10 agree.  
11 What I can't agree with is: I  
12 haven't read through this whole document. I don't  
13 know what all of it says.  
14 But on the face of it, I can't buy  
15 that you need a 20 percent share of voice, so to  
16 speak, in order to have this kind of a marketshare.  
17 Q. Can you name for me one product, that  
18 didn't have a 20 percent share of voice, that got a  
19 5 percent marketshare -- one branded product?  
20 A. I just haven't thought about it.  
21 I will get back to you.  
22 Q. Okay.

1 pieces, and this message was presented to physicians  
2 to prepare them for consumer requests."  
3 Yeah, this is page 12 of the report,  
4 under "B."  
5 You didn't mention -- and maybe you  
6 weren't given the information related to it -- that  
7 Duramed stopped the direct-to-consumer advertising  
8 promotion much sooner than they had planned.  
9 How does that factor into your  
10 opinions at all?  
11 A. I knew they stopped. I didn't know that  
12 they had stopped earlier than planned.  
13 Q. Okay.  
14 A. How does that plan?  
15 Q. No. I assume that that didn't factor into  
16 your analysis.  
17 A. (Witness shakes head.)  
18 Q. All right. You have to respond verbally.  
19 A. No.  
20 Q. Isn't it true that, with a consumer-driven  
21 message, direct to consumer is imperative?  
22 A. I don't think it's imperative. I think

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1 A. I'll think of some.  
2 Q. Please do.  
3 A. Can I keep this?  
4 Q. Yeah.  
5 MR. PARKER: Well, that's the record.  
6 So...  
7 MR. DOBIE: Well, that's the record.  
8 But we'll get you --  
9 MR. PARKER: We'll make you a copy  
10 somehow.  
11 MR. DOBIE: Is that an extra?  
12 There you go.  
13 MR. LOBB: That's the one that you  
14 gave me.  
15 THE WITNESS: Thank you very much.  
16 Q. The next part of your report, "B," you  
17 talk about Cenestin's marketing message was  
18 appropriate for each intended audience; and you  
19 mention how appropriate market research was done to  
20 position Cenestin.  
21 "Duramed aimed the 'plant based'  
22 message to consumers in initial direct-to-consumer

1 it's a -- it's nice to have.  
2 I think that the sales force calling  
3 on doctors is where it starts.  
4 And you can do direct-to-consumer in  
5 the doctor's waiting room. You don't have to do it  
6 in "Ladies Home Journal" or, you know, other  
7 publications like that.  
8 Q. The message that Duramed went with, this  
9 plant-based message, that is a  
10 direct-to-consumer-type message; you would agree?  
11 A. Yes.  
12 Q. And that message --  
13 A. But I don't think that it was totally  
14 irrelevant to physicians either.  
15 While physicians didn't make a big  
16 deal out of it, while they didn't feel that it was  
17 an important message for them, it's still the kind  
18 of thing that was perceived and remembered by  
19 physicians in the market research.  
20 Q. You're aware of the market research that  
21 indicated that only a very, very small portion of  
22 physicians cared at all about the plant-based

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1 message; right?

2 A. Well, it depends on what you call "cared

3 at all" -- or what they called.

4 And I wasn't there for the research.

5 So, yes, I don't know what the answer

6 to that question is.

7 But in terms of them having that

8 information, it was probably something that should

9 have been given to them.

10 MR. DOBIE: Have you got to change

11 the tape?

12 VIDEOGRAPHER: Um-hum.

13 MR. DOBIE: Let's go ahead.

14 VIDEOGRAPHER: The time is 1:55.

15 This is the end of Tape No. 2.

16 We're off the record and moving on to

17 Tape No. 3.

18 (A recess was taken.)

19 VIDEOGRAPHER: The time is 1:57.

20 We're back on the record. Beginning

21 of Tape No. 3.

22 MR. DOBIE: All right. Let me hand

1 Q. And it says that just 6 percent of

2 patients object to Premarin source, and 7 percent of

3 patients request a plant-derived product.

4 Do you see that?

5 A. Correct.

6 Q. All right.

7 A. Yes, I do.

8 Q. In light of the fact that physicians are

9 only reporting patient requests for plant-derived

10 product 7 percent of the time, and only 6 percent

11 objecting to Premarin source -- don't you think that

12 a marketing campaign that was aimed at telling

13 patients -- or emphasizing -- is the primary message

14 that Cenestin was a plant-derived product and that

15 Premarin was a horse-derived product was a -- maybe

16 not as good of a message as what they later came up

17 with?

18 A. The answer to your question is yes, if

19 that's the only thing that they're doing.

20 My look at the sales aids showed that

21 they were doing more than just talking about

22 plant-derived. They were also talking about the

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1 you what was previously marked as Exhibit 619.

2 And I assume that this is, maybe, the

3 document that you're referencing.

4 For the record, Exhibit 619 is the

5 "Oral Estrogen Market Overview, Cenestin Launch

6 Meeting" document.

7 BY MR. DOBIE:

8 Q. Have you seen this document before, sir?

9 A. I believe I have.

10 Q. Okay.

11 A. I don't recognize "Jeff Kern" as being on

12 the front page.

13 Q. Mr. Kern was the Cenestin brand manager.

14 You didn't read his deposition, I

15 take it?

16 A. No.

17 Q. Look at page -- it's not Bates numbered.

18 It's in maybe 10 or 12 pages. It says at the top

19 "Cenestin Qualitative Research."

20 A. Okay.

21 Q. "Physician reported patient requests."

22 A. Got it.

1 dissolution, the things that showed superiority of

2 this product over Premarin.

3 Q. Are you aware of the fact that Cenestin is

4 not 100 percent plant-based?

5 A. I am aware of that now.

6 Q. Do you know whether or not Cenestin was

7 ever 100 percent plant-based?

8 A. I don't have a clue as to what -- what,

9 when, where -- I don't know anything about those.

10 Q. Now --

11 A. And everything that I've read, by the way,

12 from the company has been that it is.

13 Q. That's what they contend -- right? --

14 throughout all the company documents, is that it's

15 100 percent plant-based?

16 A. Well, they don't contend it. I mean,

17 that's the way it reads.

18 Q. Well, you're not looking at manufacturing

19 documents or raw-material-source things -- you

20 haven't seen anything like that, have you?

21 A. No, I haven't.

22 Q. The documents you've seen are the

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1 marketing documents; right?

2 A. Yes.

3 Q. All right.

4 Now, you criticize Dr. Kolassa in his

5 statement that the change in message negatively

6 affects sales because physicians and sales reps, you

7 say, get bored and they want a change.

8 A. Yes.

9 Q. All right. Here's what I'm getting at:

10 Would you agree with me that, when

11 Solvay changed the promotional message, that that

12 was an improvement over the prior message?

13 A. Yes.

14 Q. And would you agree that it wasn't just

15 simply a new advertising campaign, it was really a

16 shift in the primary focus -- the primary message

17 that you're going to be promoting?

18 A. Yes.

19 Q. All right. And you say that Dr. Kolassa's

20 cardinal rule in marketing, that you never get a

21 second chance to make a first impression, has little

22 relevance in pharmaceutical marketing.

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1 What is the basis for that statement?

2 A. And in fact, I think I quote one of the

3 exhibits that he used --

4 Q. Um-hum.

5 A. -- where -- and my experience, by the way,

6 in the field sales force -- that nobody walks into a

7 doctor's office and makes a sale on his first call.

8 If there were a product or a sales

9 rep that could do that, he could write his own

10 ticket. I mean, this would be something that

11 everybody would want to buy.

12 The marketplace and doctors'

13 behaviors -- you know, they're used to writing a

14 particular thing for patients -- requires time and

15 the development of a relationship.

16 It requires multiple calls.

17 Q. Have you seen data about how many calls,

18 on average, is needed in order to generate a

19 prescription?

20 A. I have; but the data is dated.

21 And it's somewhere along the

22 neighborhood of -- like, on the average of five

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1 calls are required in order to make this.

2 But, here again, you're talking

3 averages. And you can't -- you can't use averages

4 in this business when you're looking at changing a

5 behavior.

6 Some doctors are hard. Some doctors

7 are easy. Some doctors don't see representatives.

8 Some doctors, excuse the impression, could be

9 married to a relative of a representative.

10 So there's a lot of things that go

11 into this.

12 Q. But having more sales calls -- strike

13 that. We've covered this.

14 Do you think you can blow a product

15 launch, that you can do such a bad job that it can

16 at least impact the uptake of your product?

17 A. Can you blow a product launch?

18 Q. In other words --

19 A. Yes, you can blow a product launch.

20 Q. I mean, here's the thing:

21 When a pharmaceutical product gets

22 FDA approval, there's a certain amount of benefits

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1 you get just from that approval.

2 And if you only -- you'd agree with

3 that; right?

4 A. You can't sell it until you get approved,

5 period.

6 Q. Right.

7 And it's published in the pink

8 sheets. And, you know, the information is out

9 there. And --

10 A. Correct.

11 Q. And if it's -- if you launch a product and

12 the launch is not -- let's just say, hypothetically,

13 if the launch is conducted by people who are

14 inexperienced, who go into a doctor's office and

15 aren't able to talk about the products and compare

16 them in a concise and cogent manner, and your

17 message that is out there promoting the new product

18 is a message that's not appealing to physicians --

19 that's something that can impact the sales of the

20 product, generally; right?

21 Would you agree with that?

22 A. You're saying -- let me see if I can

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1 repeat this.

2 Hypothetically --

3 Q. Hypothetically.

4 A. -- if the message is bad and the

5 representative doesn't know what the representative

6 is doing --

7 Q. Right.

8 A. -- and goes into the doctor's office and

9 blows it, the presentation -- doesn't know what he's

10 talking about -- can that have an impact?

11 Q. Yes.

12 A. Yes.

13 Q. And in fact, could it have a significant

14 impact to the success of the product?

15 A. You mean, a year later or during the first

16 three months or until another representative comes?

17 Q. Until they get it straightened out. Until

18 the reps are able to speak in a concise and cogent

19 manner, in terms of the attributes of the product

20 versus the competitors'.

21 MR. PARKER: Objection.

22 Q. And the message is one that isn't

1 doesn't understand sales or the product -- if your

2 question is, for that series of assumptions, could

3 it have a negative impact on the sales of the

4 product? Yes; to the extent that, someone later

5 comes in and gives the right message, it obviously

6 is -- we're talking a whole different ball game.

7 All right. So if you're talking

8 about -- the first time -- could it impact his

9 ability to make that sale, Day 1? Absolutely. But

10 nobody makes a sale on the first day anyway.

11 If you're saying that the person

12 never learned through the next -- whatever -- five

13 details on the doctor, then perhaps that could be a

14 problem as well; and hopefully, you would be looking

15 for a new representative in that case.

16 If you're talking about an individual

17 who can't do it, and then next month -- you know,

18 there's just so many "what-ifs" in this scenario,

19 that it's really hard to assess.

20 If you've got a good message a month,

21 two, three months later, it might be exactly what

22 the doctor is looking for.

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1 appealing to the intended audience.

2 Can that have an impact, a

3 significant impact, over a time period?

4 MR. PARKER: Objection.

5 You've changed the hypothetical.

6 A. Can I --

7 Q. You could answer.

8 A. Say it again, because I'm getting

9 confused.

10 Q. Let's say, even nine months out -- if you

11 still have a sales force that is not able to deliver

12 a concise, cogent explanation of a pharmaceutical

13 product's attributes, and the message to the

14 intended audience is not an applicable message --

15 can that significantly impact the uptake of the

16 product in the marketplace?

17 MR. PARKER: Objection.

18 A. And I'm having a problem, now, with the

19 word "optimal."

20 Let me state it again.

21 If you have a bad message that's

22 totally irrelevant, given by a salesperson who is --

1 "Oh, why didn't I think of that?"

2 Or if you're making a message that

3 says: Maybe the reason you're getting breakthrough

4 on your patients at night is because of the bad

5 absorption or the bad pharmacokinetic profile, which

6 is resolved with this -- blah, blah, blah.

7 And now the doctor goes, "Now I

8 understand why I should use it."

9 If that's what you're talking about,

10 it's a short-lived phenomenon. The doctor is going

11 to learn about that product over time.

12 Do I make sense?

13 Q. No; I think you do. I think you clearly

14 do.

15 And -- so I understand what you're

16 saying. I just -- here's just sort of a related

17 question:

18 What you're positing is a situation

19 where, let's say, nine months, a year out -- or

20 whatever -- the sales rep goes and it does it the

21 right way and the doctors get it. Okay?

22 What I'm wondering is:

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1 Even if they've done everything right  
2 in this time period -- the nine months out or year  
3 out or whatever -- in your experience, will the  
4 product still do a little bit worse than it would  
5 have if at the time that the FDA approved the  
6 product they had done it right, right from the bat,  
7 from the get-go?

8 THE WITNESS: Are you going to object  
9 again?

10 MR. PARKER: Um-hum.

11 A. Let me answer this question:

12 It shouldn't have any detrimental  
13 effect, other than to perhaps slow down the point at  
14 which you get that doctor's buy-in. So it could  
15 have an effect early on.

16 But I think what would have more  
17 detrimental effect is -- and maybe this is the  
18 salesman in me coming out -- but if the patient went  
19 to the drugstore and couldn't get it because it  
20 wasn't on his formulary, who cares? -- no matter how  
21 good the sales rep was.

22 Q. Oh, on the size of the sales force, page

1 But we weren't.

2 Q. What else were you looking at?

3 A. And it really gets into detailing.

4 When you have a sales force, let's  
5 say, like -- pick a sales force -- any company.

6 We talked about Celexa earlier.

7 When you've got a sales force from  
8 Forrest that's out there selling four or five  
9 different products, even though Celexa is their  
10 number one product they have to do a heck of a lot  
11 more selling of other products and take up more time  
12 in the doctor's office to sell those products than  
13 was required for the Cenestin sales force.

14 The sales force, in this particular  
15 instance, had one product to detail. So every  
16 doctor that they saw got a Cenestin detail.

17 Sales force size is important; but if  
18 they never get direction -- we had what's called  
19 "POA" and "non-POA" products at Roche.

20 "POA" products are those products  
21 that are presented to physicians, and they're broken  
22 into POAs. So that maybe of the five products that

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1 13 of your report --

2 A. Correct.

3 Q. -- you say that after adding Cardinal and  
4 Solvay sales forces together, Cenestin was detailed  
5 by over 300 sales reps. This places Cenestin in the  
6 middle of the pack, in terms of sales force size  
7 according to Dr. Kolassa's chart.

8 A. Right.

9 Q. Isn't it true that what Cenestin ended up  
10 getting was about middle-of-the-pack sales?

11 In other words, it had a  
12 middle-of-the-pack sales force. It had a brand-new  
13 product.

14 As you said before, you've got to do  
15 a certain number of detailing to reach any  
16 physician.

17 I mean, wouldn't you expect that the  
18 results would be sort of middle-of-the-pack --

19 A. I think --

20 Q. -- sales?

21 A. -- if we were just looking at sales force  
22 size, I might be inclined to go along with that.

1 we're selling, only three were going to be on the  
2 campaign for this quarter.

3 In this case, every time they made a  
4 call to a doctor they got a Cenestin detail.

5 So you got to look more at details  
6 than at sales force size.

7 Q. So it's the number of details that matter?

8 A. I perceive that it's not only just the  
9 number of details, but it's the quality of the  
10 detail, the position at which you give the detail to  
11 the physician -- at least those things.

12 Q. So whether or not you detail a physician a  
13 first or a second position, that could make a  
14 difference?

15 A. It could make a big difference.

16 Q. And if the Solvay reps were promoting  
17 Cenestin in a second position, for example, behind  
18 Estratest or prometrium, that could adversely affect  
19 Cenestin?

20 A. It wouldn't adversely, but it wouldn't  
21 affect it positively as well as if it was in a first  
22 position.

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1 Q. And you're aware, are you not, that even  
2 the Cardinal reps were not just promoting Cenestin;  
3 they were also selling Estratest and prometrium?  
4 Were you aware of that?  
5 A. Well, if you look at the audience it  
6 doesn't say that they were actually presenting any  
7 of those other products. So whether they were or  
8 not, I don't know.  
9 Q. But if --  
10 A. I was aware that they were supposed to be  
11 looking at those other products. But frankly, I do  
12 not know when that was -- when they were responsible  
13 to start to sell those.  
14 Q. And you would agree with me that to the  
15 extent -- I mean, just based on what you said a  
16 moment ago -- that to the extent that the Cardinal  
17 or Solvay sales reps were in there promoting all  
18 three products, that's not as good as if they were  
19 just promoting Cenestin; right?  
20 A. No.  
21 What I'm saying is that if your  
22 presentation for Cenestin is done while you're

1 right?  
2 A. We have a concept that's used in marketing  
3 research called "top box scores." That means you  
4 look at those that are at the top of the scale. You  
5 monitor those over time to look for changes.  
6 In these particular audits -- and  
7 it's unfortunate that I couldn't provide the Scott  
8 Levin data, because they had actual positions where  
9 the details were given in first, second, and third  
10 position -- but in these audits, what it shows is  
11 that the presentations given for Premarin and rated  
12 "excellent" was at 11.4 percent versus Cenestin  
13 presentations that achieved an excellence quality  
14 rating of 12.9.  
15 Q. Now, do you think that that might be  
16 because the doctors have heard about Premarin for  
17 the last forty-something years and that Cenestin was  
18 a new product, and therefore they're learning  
19 something new?  
20 A. I can't tell you why -- I couldn't tell  
21 you if perhaps the Premarins were Columbos on the  
22 way out from this.

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1 walking out the door -- what we used to call a  
2 "Columbo" when you sell -- if -- "Oh, Doc, did I  
3 mention Cenestin? Would you like some samples -- if  
4 that is the extent of your detail, that's not as  
5 effective as you sitting down, actually having a  
6 presentation with the physician, where you're going  
7 through features and benefits of the product.  
8 Do I make sense?  
9 Q. Let me ask you about your statements about  
10 the effectiveness.  
11 You have prepared a chart in which  
12 you --  
13 A. On page 14, now?  
14 Q. Yes.  
15 -- in which you go through IMS data  
16 on quality.  
17 A. Yes.  
18 Q. And it's your conclusion that the Duramed  
19 sales reps and the Solvay sales reps that were  
20 promoting Cenestin were rated in the IMS data as  
21 better sales calls than the Wyeth or -- I'm sorry,  
22 Wyeth or -- I guess they're Ayerst sales reps --

1 All I can say is that the doctors, at  
2 least over the year that this audit compiles data,  
3 have rated the Cenestin presentations of a better  
4 quality.  
5 Q. On a percentage basis?  
6 A. On a percentage basis.  
7 MR. PARKER: I need a break before  
8 too long.  
9 MR. DOBIE: We can break now.  
10 That's fine.  
11 VIDEOGRAPHER: The time is 2:17.  
12 We're off the record.  
13 (A recess was taken.)  
14 VIDEOGRAPHER: The time is 2:23.  
15 We're back on the record.  
16 BY MR. DOBIE:  
17 Q. I was asking some questions about pages 13  
18 and 14 of your report, in Exhibit A, having to do  
19 with the effectiveness of the Cenestin sales calls  
20 by Cardinal and Solvay.  
21 You reference on page 14 that in July  
22 of 2001 12.9 percent of the calls for Cenestin were

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1 rated "excellent," while only 11.4 percent of the  
2 calls on Premarin were rated "excellent."  
3 So the difference is 1.5 percent or  
4 so?  
5 A. Correct.  
6 Q. Is that, in your view, a difference that's  
7 significant at all?  
8 A. I honestly don't know. I don't know.  
9 I've not been working with this audit  
10 recently, so I don't know about the statistical  
11 value of it.  
12 I think that what would be important  
13 would be to trend this over time and look at it,  
14 which obviously I did not have the time to do.  
15 But you should note that this is a  
16 year's worth of information that's included here,  
17 not just the month of July -- which gives it a  
18 little bit more relevance.  
19 And they're looking at, also, 200  
20 and -- what? -- 90 -- 270-something details or  
21 presentations just for Premarin alone?  
22 That's a pretty significant number.

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1 252 or something like that.  
2 281,000.  
3 Q. Now, you don't really give an opinion  
4 about the training of Duramed's sales reps. You say  
5 that a longer training period is unnecessary when  
6 the sales force is promoting only one product.  
7 Do you know what the average training  
8 period is for the promotion of a single product?  
9 A. I know when I was -- when I was brought in  
10 and trained at Hoffmann-LaRoche, I went through --  
11 and I'm going to guess I had responsibility for  
12 seven products, maybe it was six -- my entire  
13 training was four weeks: Two weeks right when I was  
14 hired; and then another two weeks about a month, two  
15 months, later.  
16 Q. That was in 1976 or so?  
17 A. Yes.  
18 Q. Do you know how that training compares to  
19 the training that is done nowadays by --  
20 A. I can't say.  
21 Q. Does --  
22 A. I can say, though -- and I think I

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1 mentioned it in my report -- that these sales reps  
2 were all -- they all had a year's worth of  
3 experience in order to be hired.  
4 Q. A year's worth of experience, selling?  
5 A. Of selling.  
6 Q. So it could have been they were selling  
7 car parts or nails or who knows what?  
8 A. Well, I would assume it wasn't selling car  
9 parts. It was at least some kind of selling to  
10 people. Not retail selling -- but, yes, you're  
11 right.  
12 Q. I'm right, we don't know what kind of --  
13 A. I don't know.  
14 Q. And in your report, you seem to be  
15 suggesting that these folks were only promoting one  
16 product.  
17 You don't know whether or not they  
18 were also promoting Solvay's line of women's  
19 products as well?  
20 A. I know that the data, when I looked at the  
21 presentations being given for products, it only  
22 showed that they were presenting Cenestin.

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1 So if there were other products that  
2 they were presenting during the time period I looked  
3 at, it did not show up.  
4 Q. The data that you're referencing is what?  
5 A. Is end of year 2000, Scott Levin. That  
6 data I looked at. And it did not show them selling  
7 anything else.  
8 It's not in this document.  
9 They wouldn't sell me the data.  
10 Q. Have you seen any of the documents that  
11 indicate that Duramed, including its president, was  
12 concerned that, in fact, Cenestin was not being  
13 promoted in the first tier position, at least in  
14 1999?  
15 A. I don't know what the year was.  
16 I saw a document that there was going  
17 to be a discussion with David Dod and Mr. Arington,  
18 but I cannot remember the date.  
19 And I don't remember the specific  
20 memo, whether it was that they weren't doing -- or  
21 that he was looking for more.  
22 I knew there was a discussion going

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1 to take place.

2 Q. Do you think that if the sales reps were

3 more experienced, that that could -- strike that.

4 As a general matter -- all right? --

5 without getting into whether they were trained right

6 or weren't trained right -- would you agree that,

7 generally speaking, having sales reps properly

8 trained can impact the success of the sales calls

9 with the physicians?

10 A. I think that having sales reps trained

11 appropriately is important, if that's what you're

12 asking me.

13 Q. "Important," in terms of generating

14 prescriptions?

15 A. Yes.

16 Q. And let's talk about samples.

17 You talk about the use of the 30-day

18 sample versus the seven-day sample.

19 Let me ask you generally first: What

20 is the purpose of samples, from a pharmaceutical

21 marketing standpoint?

22 A. Well, I do get into that in my report; and

1 companies, those products that have samples in the

2 past or have physicians' behaviors already

3 entrenched -- will be a lot more difficult to change

4 those trends without having samples.

5 Do I --

6 Q. Let me ask you a follow-up question on

7 that.

8 The samples -- how are they used by

9 the sales reps when they're detailing the

10 physicians?

11 A. How are they used? That depends.

12 It frankly depends on the sales rep,

13 as much as anything.

14 For the intended use, a sales rep

15 would use them perhaps during his presentation -- to

16 put them out and make it a focal point while he's

17 talking about it with the doctor.

18 He might try and say, "Doctor, is

19 this enough to start your next ten patients on

20 Premarin or Cenestin?" or something like that? "Do

21 you need more?"

22 I mean, they can use them as a sales

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1 I certainly did not present an exhaustive list.

2 The purpose of providing samples to a

3 physician is, one, so that he -- and most

4 importantly -- will think about your product when he

5 walks to the closet -- to the sample closet -- and

6 maybe pull your drug down and give to it a patient,

7 and for the physician and the patient to gain

8 experience.

9 Now, as I also mentioned there's a

10 different value over time to samples.

11 Samples, when you're -- when you're

12 going out and wanting to gain a physician's

13 experience, may not have the same motivations that

14 you would have in a sample for a product that you

15 had around for years and years, and may or may not

16 have competition to.

17 For example, Premarin could have --

18 and I would not suggest that they don't offer

19 samples -- but they wouldn't be impacted to the same

20 extent as Cenestin bringing a new product to market.

21 If there was a law that said that no

22 more samples will be given to physicians by drug

1 tool.

2 They can use them, as I said in the

3 report, as a shelf kind of thing -- just so that

4 they're in front of the shelf, in front of the

5 doctor's mind.

6 But the most appropriate use that a

7 doctor and a pharmaceutical company would like to

8 see for these products is to gain experience early

9 in a product's life cycle, gain experience with the

10 product. Get the patient to go out and try the

11 drug, see if it works.

12 Q. In your experience, are samples used by

13 reps -- are they expected to be distributed to the

14 doctors when they make the sales call?

15 A. Usually, yes.

16 What you will find is: There are

17 sales reps that may want to use them for other

18 purposes.

19 And I'm not speaking illegal

20 diversion or things like that.

21 But let's say you've got a company

22 like Wyeth -- and, please, this is not meant as a

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1 negative -- but a product, as you mentioned earlier,  
2 that -- do you think maybe the doctor is tired of  
3 the message?

4 So the representative will go in  
5 there and just say, "Hey, Doc, do you need more  
6 samples?" And then on his call report to the  
7 company -- "Yep, I sold Premarin to this doctor, had  
8 a detail for Premarin with this doctor."

9 So when you asked me, how are they  
10 used by salespeople? -- it's a really difficult  
11 question to answer, because they could have a lot of  
12 different ways that they're using these things.

13 Q. Is it your experience that physicians view  
14 samples, to some extent, as part of the ticket to  
15 entry?

16 In other words, they expect you to  
17 bring samples if you're going to be detailing a  
18 product so that they can, in fact, try the product  
19 out with their patients?

20 A. Certainly for a new product, yes.

21 Q. And do you think that if the samples,  
22 instead of being brought, are instead mailed in

1 They have a specialty sales force, of  
2 which my son used to belong; and he, as well as  
3 another sales rep in that company, have told me that  
4 multiple samples are typically given to people, not  
5 seven-day -- even though they have a seven-day  
6 sample pack -- their product is packaged that way --  
7 but that that's not the way the doctors use it.

8 And by the way, the documents that I  
9 reference in here from Wyeth even mention that they  
10 wanted to go to a 30-day sample.

11 Typically, in this marketplace a  
12 doctor wants the patient to have enough experience  
13 on the drug; and it doesn't work in seven days.

14 So for a new patient coming in, you  
15 want to gain that experience, and make sure that  
16 you've got the right product and the right dosage  
17 and everything else.

18 And that's why I say, for Wyeth --  
19 it's not as important, for a company like Wyeth,  
20 where your doctor is probably giving the sample out  
21 for patients that only need to get over a couple of  
22 days while they're waiting to get to the pharmacy or

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1 bulk -- you know, months later, for example -- that  
2 that could impact the success of the sales calls  
3 with the physicians?

4 A. It could.

5 Q. The sampling that you talk about here, you  
6 talk about how in your view it was appropriate to  
7 use a 30-day-sample pack rather than a  
8 seven-day-sample pack.

9 A. For this particular product in this  
10 particular point in time, yes.

11 Q. And why do you believe that?

12 A. For a couple of reasons.

13 This particular market -- let me drop  
14 back a foot.

15 My son works for Parke-Davis. My son  
16 launched FemHRT.

17 He works for Pfizer now. He no  
18 longer sells FemHRT because the  
19 primary-care-physician audience is no longer one of  
20 their targets.

21 This is something Wyeth does not  
22 know -- yet.

1 waiting for their mail-order prescription to come --  
2 seven days is sufficient.

3 Q. You said a lot of things there. So I want  
4 to make sure that we cover them.

5 A. I hope not too much.

6 Q. You said that Wyeth wanted to go with a  
7 30-day sample.

8 There's one person in one document  
9 that you're referencing that suggests a 30-day  
10 sample; right?

11 A. That is correct.

12 Q. And do you know whether or not --

13 A. I don't know that it was one person or --  
14 it looked to me like a presentation.

15 Q. Do you know what happened to that  
16 presentation or what was done with that suggestion?

17 A. Certainly not.

18 Q. Do you know whether or not Wyeth ever went  
19 with a 30-day sample for Premarin?

20 A. I don't think it makes sense for Wyeth to  
21 do it.

22 Q. Do you think it makes sense for Duramed to

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1 have -- do you think it would have made sense for  
2 Duramed -- strike that.  
3 First, you don't know whether or not  
4 Wyeth ever went with a 30-day sample?  
5 A. Absolutely, I do not.  
6 Q. And do you know whether, in fact, Duramed  
7 went with a seven-day sample once they were able to  
8 do it?  
9 A. I don't know that.  
10 Q. And do you think that if they were  
11 projecting selling 600,000 30-day packs in 1999, and  
12 instead they gave away that same number -- that that  
13 could have impacted what their sales were in the  
14 first year?  
15 A. I think that those are two disjointed  
16 things we're talking about: 600 samples -- 600,000  
17 sample packs versus 600,000 bottles that they hoped  
18 to sell.  
19 If they got physicians to use those  
20 samples as samples, then they would have sold a lot  
21 more than 6 percent.  
22 Do I make sense?

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1 Q. Well, I'm not sure.  
2 If they had projected in the course  
3 of a whole year that they were hoping to sell  
4 600,000 bottles of Cenestin, and instead they gave  
5 600,000 away for free -- 30-day samples -- don't you  
6 think that might have impacted what their sales  
7 were?  
8 A. I would think that possibly they were  
9 thinking: If I gave away 600,000, maybe I'll get 50  
10 percent marketshare.  
11 Q. So here's the point:  
12 It might have come back in subsequent  
13 years to their benefit; but it certainly could have  
14 impacted what the sales were in the first year.  
15 Right?  
16 A. I'm missing the point.  
17 To me a sample is a starter pack.  
18 It's used to get a patient started and acclimated on  
19 a product.  
20 It's not used to fill the channel,  
21 and they aren't getting to the shelf.  
22 If they are getting to the

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1 prescription shelf in the pharmacy, then there is  
2 something illegal going on. That shouldn't be where  
3 they're at.  
4 It's meant to motivate a prescription  
5 from a physician.  
6 Q. You mentioned FemHRT, and you mentioned  
7 your son's experience with seven-day versus 30-day  
8 samples.  
9 Do you know what percentage of the  
10 FemHRT samples are seven days versus 30 days?  
11 A. I have not -- I do not know.  
12 I would guess that a large percentage  
13 of them were seven-day.  
14 Q. The other products that are in the ERT  
15 category -- do you know whether or not they, as a  
16 rule of thumb, use seven-day samples?  
17 A. No, I do not.  
18 Q. Do you know whether they use 30-day  
19 samples?  
20 A. No, I do not.  
21 Q. Do you know whether there is anybody in  
22 the ERT marketplace that uses anything other than

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1 seven-day samples, with the exception of Duramed's  
2 30-day sample?  
3 A. I do not.  
4 Q. If the president of Duramed testified that  
5 he believed that the use of 30-day samples would  
6 have slowed the uptake in prescriptions of the  
7 product, do you just disagree with that?  
8 A. Say that again.  
9 Q. If the president of Duramed testified that  
10 he believed that the use of 30-day samples slowed  
11 the uptake of prescriptions, you'd just disagree  
12 with that?  
13 A. No, I don't.  
14 Q. If the director of marketing for Duramed  
15 stated the same thing, would you disagree with that?  
16 A. No.  
17 Q. The discussion that you have here about  
18 the relative cost of a 30-day versus a seven-day  
19 sample -- would you explain that for us, please?  
20 A. The active-ingredient cost for most  
21 prescriptions -- most prescription products -- will  
22 fall somewhere between 3- and \$4.

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1 And that's not just active  
2 ingredients. That's what it costs to actually --  
3 from raw material, purchasing of raw material, to  
4 the actual production of a bottle of 100 tablets.  
5 The packaging costs are typically  
6 looked at as about \$1.  
7 And that's for components. That's  
8 for the bottle, the cap, the safety cap, the label,  
9 the package insert.  
10 And some people package them in  
11 boxes. It could be a little bit more expensive.  
12 That's going to be about \$1.  
13 Now, when you blister-pack it's even  
14 more expensive -- because you've got to go through a  
15 process of not only packaging this, but you've got  
16 to worry about --  
17 Your materials are an independent  
18 process. It's a smaller-batch kind of process.  
19 But the bottom line is: It's about  
20 \$1. Whether you're packaging 100 or you're  
21 packaging seven, it's going to be about \$1.  
22 So if -- my point is: If you are

1 Q. Uh-huh.  
2 A. No.  
3 Q. Do you know, in total, how many sales reps  
4 were engaged to promote FemHRT?  
5 A. I do not.  
6 I know how many were at Parke-Davis  
7 was -- I take that back. I'm not 100 percent  
8 certain I know about Parke-Davis.  
9 Q. What is your best estimate of how many  
10 were at Parke-Davis?  
11 A. Well, I was told the Women's Healthcare  
12 Group was only 150 people.  
13 Q. And the product was jointly promoted with  
14 Pfizer, though; right?  
15 A. Not when they launched it.  
16 Q. When did they begin jointly promoting it?  
17 A. When Pfizer bought them.  
18 Q. When was that?  
19 A. Pfizer bought Warner-Lambert -- what? --  
20 two years ago.  
21 Q. So some point in 2000?  
22 A. I'm really guessing.

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1 going to take 30 tablets, let's say, and break them  
2 into packages of seven, you're looking at somewhere  
3 in the neighborhood of 90 cents' worth of  
4 ingredients' cost in that 30, and \$1 for the  
5 package.  
6 So you're talking about \$1.90,  
7 something along those lines, for a bottle of 100 --  
8 versus -- if you're talking the three different  
9 packages -- you're talking for that same 30, \$3 just  
10 in packaging costs.  
11 Actually -- I take that back -- \$4.  
12 Twenty-eight tablets would be four  
13 packages; correct?  
14 Q. You mentioned "FemHRT" a moment ago.  
15 Do you think that that's a good  
16 benchmark for what Cenestin should have done in the  
17 marketplace?  
18 A. I honestly don't know. I haven't looked  
19 at it. I have not attempted to.  
20 Q. Do you know how many sales reps Pfizer had  
21 promoting FemHRT?  
22 A. Do I know how many Pfizer had?

1 Sometime between '99 and 2000.  
2 Q. Page 17, you say: "While I agree that  
3 it's the standard practice in the pharmaceutical  
4 industry for drug manufacturers to enter into rebate  
5 contracts, several aspects of Wyeth's contracts take  
6 them outside of the norm."  
7 Okay. Now, first, in terms of what  
8 the "norm" is on branded pharmaceutical companies'  
9 rebate contracts -- the experience that you  
10 identified for us this morning was the experience  
11 that you had at Hoffmann-LaRoche; right?  
12 A. Bristol-Myers, not --  
13 Q. And Bristol-Myers?  
14 A. And -- as well as my experience at Teva.  
15 That's it.  
16 Q. And the rebate contracts that you're  
17 referencing at Teva -- we talked about that this  
18 morning -- that related to a generic product; right?  
19 A. Yes.  
20 Q. And at Bristol-Myers, I think you told me  
21 you weren't aware of what the rebate contracts were  
22 on the Estrace products; right?

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1 A. Correct.

2 Q. And what rebate contracts are you familiar

3 with at Bristol-Myers, if any?

4 A. I wouldn't be aware of any of them now.

5 The only -- none.

6 Q. All right. And at Hoffmann-LaRoche, what

7 rebate contracts are you familiar with?

8 A. None.

9 Q. So when you say that the contracts are

10 outside the norm, what's the basis for that

11 statement?

12 A. My industry experience and going to --

13 having discussions with these individuals.

14 I have talked -- whether it was with

15 brands or generics, I still talk with the

16 individuals; have friends at PCS, as a matter of

17 fact.

18 So, it's discussions with them.

19 Q. But in fairness -- I mean, do you think --

20 these contracts are not publicly-available

21 contracts, are they, generally?

22 A. No.

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1 Q. And in fairness, do you really think you

2 have an understanding of the ins-and-outs of these

3 contracts, such that you can give expert testimony,

4 under oath, as to what the "norm" is for rebate

5 contracts from 1991 to the present?

6 A. I would not hold myself out to that.

7 You're correct.

8 Q. All right. Now, you state in that

9 paragraph 17, under "First," that the bundling is

10 more accepted in the generic industry because

11 generic products are available from multiple sources

12 and are interchangeable.

13 What is the source for that?

14 A. My experience and discussions with people

15 at PBMs.

16 Q. So, generics -- they do bundle those?

17 A. Generics are bundled; but you don't -- you

18 don't sell generics, principally, to PBMs.

19 Q. I see. So they would be bundled at GPOs

20 and --

21 A. Exactly.

22 Q. I understand.

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1 Now, the exclusivity -- you say:

2 "It's not a standard practice in the industry for a

3 drug manufacturer to have exclusive contracts with

4 virtually every major PBM and MCO."

5 Is it your belief that Wyeth had

6 exclusive contracts with virtually every major PBM

7 and MCO?

8 A. It's my belief that Wyeth had contracts

9 that required exclusivity, whether they were called

10 "sole source" or were contracts that had rebates

11 assigned to them, such that they would lose their

12 funding, yes.

13 Q. So between contracts that talk about sole

14 source of conjugated estrogen and rebate

15 contracts -- those together, those are where you're

16 saying that Wyeth had them with virtually every

17 major PBM and MCO?

18 A. With the major, yes.

19 Q. Now, I assume that you read in

20 Dr. Kolassa's report where he had examples of

21 different products, where there was exclusive

22 contracts, rebates.

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1 You mentioned before your work with

2 AstraZeneca. We talked about the PPI category

3 briefly.

4 But you'd agree with me that there

5 are other situations in the marketplace where folks

6 have rebate contracts and exclusivity in the PPI

7 category, with Cox-2 inhibitors, with insulin, with

8 growth hormones, with certain urinary -- I got to

9 think of the name of the product --

10 A. "Ditropan"?

11 Q. -- that those were all situations where

12 you may have exclusives and rebate contracts?

13 A. I agree that all of those can have rebate

14 contracts or might have rebate contracts; but I

15 can't say that I've looked at all of those to find

16 out if they do or they do not have exclusives.

17 Q. Oh, the next paragraph, "Third" -- you

18 say: "It is not standard practice for a drug

19 manufacturer to refuse to renegotiate a contract if

20 an MCO or PBM wants to add another formulary agent,

21 as was the case with Wyeth's refusal to renegotiate

22 with Express Scripts."

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1 And let me ask you about that.

2 You mentioned the Sally Miller

3 e-mail -- that you're familiar with that, on Express

4 Scripts.

5 Are you aware of any information that

6 suggests that Express Scripts asked to renegotiate

7 its contract with Wyeth?

8 A. I read somewhere that they had mentioned

9 to Wyeth that they had gotten -- and I don't think

10 it was in Sally Miller's memo -- but that they had

11 gotten requests from a rather -- how do I want to

12 put this? -- vocal group of physicians, requesting

13 that Cenestin be added to the formulary -- something

14 along those lines.

15 Q. Right.

16 A. And that they wanted to renegotiate the

17 contract.

18 Q. You think that was for Express Scripts?

19 A. I think that was for -- I could be wrong.

20 I think that was for Express Scripts,

21 yes.

22 Q. I think I asked you this already:

1 Q. You say that -- "It is quite apparent that

2 physician requests to have Cenestin added to the

3 formulary were unavailing for even these large

4 market participants."

5 What are you relying upon here?

6 A. Those documents -- like, Sally Miller

7 document -- even though the doctors asked for it,

8 they weren't going to get it.

9 Q. So that's Express Scripts and Prescription

10 Solutions.

11 Is there anything else?

12 A. Oh, no.

13 Q. The next heading that you've got here is

14 on "Wyeth Preemptive Plan."

15 A. Correct.

16 Q. Just as we talked about this morning with

17 Sigma-Tau, your other company -- you don't in any

18 way dispute the idea that even a market leader, just

19 like your company, has the right to vigorously

20 defend its market?

21 A. "To vigorously defend its market"?

22 Absolutely not.

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1 You weren't aware of the fact, when

2 you prepared this report, that, in fact, Express

3 Scripts then added Cenestin to formulary?

4 A. Well, I was aware that they added it, but

5 then took it off.

6 Q. Right. And then they added it back on;

7 you were not aware of it?

8 A. I was not aware that they added it back

9 on.

10 You're saying it's on now?

11 Q. (Counsel nods head.)

12 A. When did they add it back on?

13 Q. The following year.

14 A. So, this year?

15 Q. No; in 2000 -- fall of 2000.

16 Prescription Solutions, are you aware

17 of whether or not there was any request on the part

18 of Prescription Solutions to renegotiate?

19 A. I read a memo that went to Taka Tomo along

20 those lines.

21 I think I'm -- I think that's the

22 right individual.

1 Q. And it's standard practice to anticipate

2 and respond to competition?

3 A. Yes.

4 Q. And forecasts regarding the impact of a

5 new entrant in the marketplace, those are typical?

6 You, in fact, do those type of forecasts?

7 A. Yes.

8 Q. And is it a standard practice to develop

9 an action plan to respond to a new entrant?

10 A. Yes. I would say yes.

11 Q. And would that include education of the

12 sales force and developing sales materials?

13 A. It would.

14 Q. At the top of page 19, you say: "Wyeth

15 was not competing on price."

16 And then you talk about how Duramed

17 documents show that the rebated prices for Cenestin

18 were in some instances far below rebated prices for

19 Premarin.

20 Were you shown the documents that

21 showed just the opposite -- that in many instances,

22 Wyeth's Premarin prices were below Cenestin's?

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1 A. No.

2 And by the way, they weren't

3 referenced in Kolassa's document. Even Kolassa's

4 document showed that prices were lower -- or

5 rebates, if you will, were larger -- for the

6 Cenestin product than for Wyeth's product.

7 Q. Have you reviewed Dr. James's report that

8 looks at all of the publicly available --

9 A. I don't know Dr. James.

10 Q. -- the available data regarding price?

11 A. No.

12 Q. Can you give me an example where

13 Cenestin's rebated price was lower than Premarin's?

14 A. I believe I made reference to a couple of

15 them in here.

16 I want to say Express Scripts was one

17 of them, I think.

18 I'm not sure about Prescription

19 Solutions. I don't remember the actual...

20 Yeah, Prescription Solutions.

21 Q. Now, you talk in the next sentence about,

22 in the case of Aetna, Wyeth shared part of the

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1 preemptive plan with -- I guess -- with Aetna and

2 the Cenestin impact model to demonstrate to Aetna

3 the rebates on all Wyeth products that would be lost

4 if the marketshare was moved to Cenestin.

5 A. And that should be all products that were

6 on their formulary.

7 Obviously, not all Wyeth-Ayerst

8 products.

9 Q. Let me ask you about that.

10 The other products that Aetna had on

11 formulary were things like oral contraceptives;

12 right?

13 A. Some of it.

14 I don't remember the specific

15 products for each company; but they would include

16 things like their Effexors, their NSAID products,

17 they're antidepressant products -- those kinds of

18 things.

19 Q. And there's a tremendous amount of

20 competition within, let's say, the antidepressant

21 category -- between Effexors and Prozac's --

22 A. All their product lines are competitive, I

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1 think.

2 Q. All right. And so if Aetna wanted to

3 cancel their contract with Wyeth and go with

4 Cenestin instead, they could still put an oral

5 contraceptive from Johnson & Johnson on formulary.

6 They could buy antidepressants from Eli Lilly. They

7 could do -- they could cut similar deals as they did

8 with Wyeth; right?

9 A. Well, that's a two-part question.

10 Yes, they could cancel the contract;

11 but they're a public company, for the most part.

12 Most of these are public companies.

13 And the question is: Are you going

14 to be willing to give up -- I mean, in the one

15 instance Sally Miller -- which didn't jive, by the

16 way with the report -- mentioned that I think it was

17 Express Scripts or -- would lose 40 million -- no,

18 it wasn't Express Scripts, it was someone else --

19 but would lose \$40 million in rebates if they put

20 Cenestin on formulary. I mean, that was the

21 implication.

22 And as a public company, can you

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1 afford to do that kind of thing?

2 Q. Here's what I'm getting at:

3 If you're an Express Scripts --

4 you've got a contract with Johnson & Johnson already

5 anyway, don't you?

6 A. Correct.

7 Q. And you've got a contract with Eli Lilly

8 already anyway; right?

9 A. Correct.

10 Q. And they'd be more than happy to sell you

11 their oral contraceptives rather than Wyeth's or

12 their antidepressants rather than Wyeth's; right?

13 A. Correct.

14 Q. So all you would be doing would be

15 switching from a "Wyeth-rebated" product to

16 "Johnson-&-Johnson-" or "Eli-Lilly-rebated" product?

17 A. Let me say that that's easier said than

18 done.

19 I don't know how long it's going to

20 take for you to get those contracts done.

21 Contracting takes time.

22 I don't know what the prices will be

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at which they're going to rebate those products.

I think that, in the case of a lot of these companies, you've worked with a manufacturer to develop promotional campaigns and things to help move products.

It would be not in either person's interest to see that these things just evaporate or that your efforts and costs just -- or rebates -- just go away.

And even if they were the same thing, if we used that example -- although \$40 million is inflated -- if we used that example and take that over a couple months' worth of time -- you know, if three months you're talking about \$12 million.

You're losing \$12 million while you're going -- converting from one to the next.

Now, you're also putting out all these new books and everything, and promotional materials that you've already got in the marketplace.

It's not the kind of thing that is -- you know, you just turn on a dime and, you know, you

We're not throwing the rebates for all of these other products into the mix -- which you are, when you're saying Premarin is sole source.

Q. But because of that, would it be -- I mean, if you're correct that there was a sole-source contract with Express Scripts that prevented Cenestin from being placed on formulary -- and let's set aside what happened in the fall of 2000 -- the fact of the matter is: They wouldn't necessarily lose all of those rebate dollars, because they could, number one, sign a rebate contract with Duramed for Cenestin; and they could sign a rebate contract with Eli Lilly or Johnson & Johnson for the Effexors and oral contraceptives; right?

A. This is really theoretical.

Q. Yes.

A. Theoretically, they could do all those things. But theoretically, they could also do them and lose money -- as opposed to what they had going on in the past.

Q. Or theoretically, they could make money -- if Eli Lilly or Johnson & Johnson offered them a

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"close-this-window-and-open-this-door" kind of thing.

Q. So another company, like a Johnson & Johnson, on oral contraceptives -- or Eli Lilly -- they'd have to be very aggressive if they were going to get that oral contraceptive or antidepressant market away from a Wyeth -- right? -- because of those costs?

A. Well -- now we're talking the difference. Now we're talking about Johnson & Johnson going at them.

Q. Yes.

A. The deal with -- at least as I understood these contracts, was: None of those products were sole source.

The only one that requested sole source was Premarin.

So if a Johnson & Johnson comes in with their conception-control, birth-control pill and they want to make a switch, it's strictly -- here's an up and up -- you know, it's based on price, period.

better deal, and Cenestin did as well?

A. Well, they typically are going to be -- yes. The answer to your question is yes.

Q. What you're saying in your report is that none of these managed-care organizations could renegotiate.

Other than the situation with Prescription Solutions and Express Scripts, are you aware of any other managed-care organizations that sought to renegotiate and Wyeth refused?

A. I have not seen -- no.

Q. In your conclusion of your report --

A. But what I did see was the document that was prepared by Wyeth with those contracts in the model and all of the individuals.

And they very clearly are all organized the same way, showing: Here's what you lose -- and they included a lot of organizations -- here's what you lose if you decide to take on Cenestin.

Q. Do you know whether or not those documents were ever used with any managed-care organization,

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1 other than Aetna?

2 A. I don't.

3 Q. At the conclusion of your report, you say

4 that Dr. Kolassa views that the deficiencies of

5 Cenestin and the marketing efforts of Duramed and

6 its partners were wholly responsible for the low

7 sales of Cenestin, and you view that that's not

8 correct in your opinion.

9 A. Correct.

10 Q. Would you agree that it could be at least

11 partly responsible for some of those low sales?

12 I don't even want to call it "low

13 sales," but just --

14 I've showed you today IMS data.

15 We've looked at the government report.

16 Don't you think that spending less

17 money than what they spent, having this being the

18 very first time that they had ever sold a branded

19 product, a brand-new sales force out there -- that

20 that could at least be partly responsible for what

21 the sales are that they, in fact, achieved?

22 A. Let me answer that question this way:

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1 I think that if they were to spend

2 more money they could potentially get more sales;

3 but let me also premise that by, they weren't

4 looking to set the world on fire. They were looking

5 for a 6 percent share of this marketplace.

6 So, I really don't know how to answer

7 your question.

8 MR. DOBIE: Let's take a break. Let

9 me go through my notes.

10 VIDEOGRAPHER: The time is 3:09.

11 We're off the record.

12 (A recess was taken.)

13 VIDEOGRAPHER: The time is 3:17.

14 We're back on the record.

15 BY MR. DOBIE:

16 Q. A few last questions on your background.

17 We talked about your educational

18 background. What formal training have you had, from

19 an education standpoint, on pharmaceutical

20 marketing?

21 A. What educational?

22 Q. Yes.

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1 A. Other than going to courses that are

2 offered in the MBA programs -- you know, like the --

3 there are market research courses held by the bases

4 group that used to be held. I used to go to those.

5 I was a member of PMRG.

6 I did start an Executive MBA program,

7 but left that to accept my position at -- in the

8 home office -- besides the fact that it was taking

9 up too much of my time.

10 Just mostly -- and -- mostly just

11 classes, things that would be provided for me --

12 week-long classes on forecasting methodologies --

13 those kinds of things -- financial planning for

14 non-financial managers.

15 When I was at Bristol-Myers, we were

16 required to go through two of those training

17 programs a year; and in my case, not only did I go

18 to those but I also went to some of the off-site

19 programs.

20 I was involved in the recruiting

21 effort for the MBA students and MBA programs at

22 Bristol-Myers. We used to bring in business

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1 interns.

2 As a matter of fact, a lot of the

3 executives that are in Bristol-Myers today went

4 through the program where I used to actually

5 interview the candidates for bringing into the

6 company.

7 So those kinds of things, I guess I

8 would say.

9 Q. But recruiting MBAs isn't --

10 A. No. Talked about programs as well.

11 Q. But as an undergraduate -- in your

12 undergraduate education, did you ever have a class

13 in pharmaceutical marketing?

14 A. No.

15 And when I went to school, there was

16 no such thing as a class in pharmaceutical

17 marketing.

18 Q. What marketing classes did you have?

19 A. Just the ones that I took in my -- in the

20 Executive MBA when I started.

21 And I did not finish them.

22 Q. So undergrad, there were no marketing

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1 classes?

2 A. Nope.

3 Q. And then in the MBA program, you started

4 some classes but didn't finish them?

5 A. Correct.

6 Q. And then the classes that you were

7 describing along the way in your career, were those

8 classes that took place at Bristol-Myers?

9 A. Well, Bristol, as well as

10 Hoffmann-LaRoche. And --

11 Q. Bristol, let me start there. Were those

12 in Syracuse?

13 A. No; those were in Evansville.

14 Q. Where was the Executive MBA program that

15 you were --

16 A. Florida Atlantic University.

17 Q. I met another graduate from there

18 recently.

19 A. They were one of the first with the

20 Executive MBA program. They're very good.

21 Q. Hoffmann-LaRoche, where were those classes

22 held?

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1 A. Oh, my gosh. I couldn't tell you.

2 I mean, we had our own institute for

3 small things; but I can't tell you where I went for

4 classes.

5 Q. All right. I mean, during the time that

6 you were at Bristol taking classes, and

7 Hoffmann-LaRoche -- I think you told us that you had

8 four weeks of training, when you started at

9 Hoffmann-LaRoche, on sales training.

10 With all of these classes that you

11 took at Hoffmann-LaRoche, how many weeks of classes

12 would you have had in total?

13 A. A typical class at Hoffmann-LaRoche would

14 be a week.

15 For example, if you were taking a

16 targeted selection course -- management training --

17 or if you were going through an assessment center --

18 these are typically week-long kinds of events.

19 Q. You do, like, one a year?

20 A. Yes; but we'd also do off-campus kinds of

21 things.

22 Q. At Hoffmann-LaRoche, that training would

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1 involve issues beyond pharmaceutical marketing.

2 You would be studying, I assume --

3 like you said -- management issues, generally;

4 financial planning -- things like that. Or would

5 you say you had one class per year on pharmaceutical

6 marketing?

7 A. No. I think you're right. I think

8 you're -- there would be general.

9 Q. And how about at Bristol-Myers; the same

10 sort of deal?

11 A. Pretty much the same -- same kind of

12 thing.

13 Q. About once a year, and a variety of

14 management courses?

15 A. Well, yes.

16 But you've got to understand that you

17 get -- the education that you get by being there --

18 for example, when I was at Hoffmann-LaRoche, we were

19 looking at -- and we had this downsizing that you

20 referred to earlier -- we wanted to look at: What

21 would be the appropriate sales force size? -- etc.

22 Those kind of questions would come

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1 into, perhaps, a marketing research.

2 In my capacity, I participated in

3 that program and designing, actually, how big the

4 sales force should be, along with the general

5 manager of the company --

6 Q. So that's --

7 Go ahead.

8 A. So -- yeah, that's on the job.

9 But the real education that you're

10 going to get in this industry typically comes from

11 there.

12 Q. Understood. Understood.

13 And I don't mean to denigrate that in

14 the least. I'm just trying to understand, in terms

15 of classes -- because I understand the on-the-job, I

16 think.

17 A. Correct.

18 Q. So set aside on-the-job training.

19 In terms of class training at

20 Bristol-Myers, would you say the same sort of thing:

21 About once a year, a variety of different management

22 courses, including pharmaceutical --

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1 A. Twice a year.  
2 Q. Twice a year.  
3 -- pharmaceutical management?  
4 A. Correct.  
5 MR. DOBIE: Understood.  
6 Nothing else.  
7 MR. PARKER: Thank you.  
8 VIDEOGRAPHER: The time is 3:24.  
9 This is the end of today's  
10 deposition.  
11 (Whereupon, signature not having been waived, the  
12 taking of the deposition concluded at 3:24 p.m.)

13 \* \* \*

14  
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1 CERTIFICATE OF NOTARY PUBLIC  
2 I, Susan D. Ashe, the officer before  
3 whom the foregoing deposition was taken, do hereby  
4 certify that the witness whose testimony appears in  
5 the foregoing deposition was duly sworn by me; that  
6 the testimony of said witness was taken by me in  
7 stenotype and thereafter reduced to typewriting  
8 under my direction; that said deposition is a true  
9 record of the testimony given by said witness; that  
10 I am neither counsel for, related to, nor employed  
11 by any of the parties to the action in which this  
12 deposition was taken; and further, that I am not a  
13 relative or employee of any attorney or counsel  
14 employed by the parties hereto, nor financially or  
15 otherwise interested in the outcome of the action.  
16 Dated: October 17, 2002  
17  
18 Notary Public in and for the  
19 District of Columbia  
20 My commission expires:  
21 April 14, 2007  
22

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1 IN THE UNITED STATES DISTRICT COURT  
2 FOR THE SOUTHERN DISTRICT OF OHIO  
3 WESTERN DIVISION AT CINCINNATI  
4 - - - - - x  
5 DURAMED PHARMACEUTICALS, INC., :  
6 Plaintiff, :  
7 vs. :  
8 WYETH-AYERST LABORATORIES, INC., :  
9 Defendant. : PAGES 1 - 275  
10 - - - - - x  
11 I, Paul Simon, do hereby acknowledge I have  
12 read and examined the foregoing pages of testimony,  
13 and the same is a true, correct, and complete  
14 transcription of the testimony given by me, and any  
15 changes and/or corrections, if any, appear on the  
16 attached errata sheet signed by me.  
17 \_\_\_\_\_  
18 Date Paul Simon  
19 SUBSCRIBED AND SWORN TO before me  
20 this \_\_\_\_\_ day of \_\_\_\_\_, 2002.  
21 \_\_\_\_\_  
22 Notary Public

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\$1 [23:4] [184:14] [245:6,12	<b>1079</b> [4:15] [156:20] [157:2	[166:8,9] [175:7] [196:20]	<b>4</b> [27:11] [98:18,22] [109:2]
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<b>\$1.90</b> [246:6]	<b>1080</b> [4:17] [187:19,22]	[254:15] [263:8]	<b>40</b> [29:12] [176:20] [177:2]
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